U.S. DEPARTMENT OF ENERGY

Commercial Grade Dedication

DOE TRAINING

Commercial Grade Dedication Training

MODULE 1

Overview of CGD Process

Course Objectives

- Define the terms “commercial grade item” and “commercial grade services”
- Understand the process for commercial grade dedication (CGD)
- Describe the bases for implementing each element of the generic process and how they relate to NQA-1 requirements and Electric Power Research Institute (EPRI) Guidelines
- Describe each element of the process and its purpose
- Understand the acceptance process for items and services

Course Content and Structure

- Module 1 – Overview of CGD Process
- Module 2 – Technical Evaluation
- Module 3 – Acceptance Planning
- Module 4 – Dedication Package
- Module 5 – Sample Selection Methodology
- Module 6 – Supplier Dedication Oversight
- Module 7 - Overview of CGD Process of Computer Program and Digital Equipment
- Module 8 – CGD Implementation and Lessons Learned

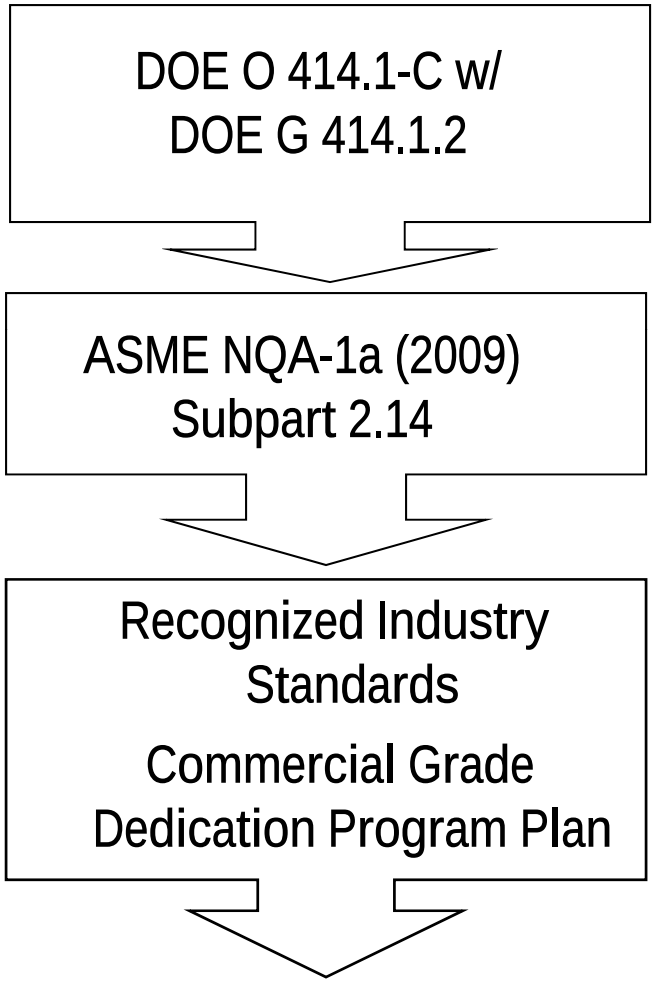
Introduction

- What is the purpose of dedication?
  - Dedication is performed to establish the acceptability of an item to perform its safety function.
- How is dedication performed?
  - Dedication consists of a technical evaluation of an item/service followed by establishment of acceptance methods.
- What is needed to start the dedication process?
  - The design must be completed to the point that the suitability of the item for its intended application has been established.

Introduction (cont)

- When is Dedication of an Item Planned?
  - Dedication planning should be part of the procurement strategy.
- How much is enough?
  - The selection of critical characteristics (CCs) is commensurate with the complexity, application, function, and performance of the item or service for its intended safety function. This decision is based on engineering judgment. It is important to document this basis.

How does the CGD process meet the requirements of DOE O 414.1C?



DOE Order 414.1C states that a national/consensus standard(s) must be chosen for implementation. NQA-1 a-2009 Part 1 and Part 2 provide requirements for implementing EPRI guidance for CGD. DOE G 414.1.2 Quality Management System Guide (for use with 10 CFR 830.120 and DOE O 414.1) – Commercial Grade Items intended for use in nuclear safety applications should be procured in accordance with documented processes using recognized consensus standards.

NQA-1 Quality Assurance Requirements for Nuclear Facilities Applications – Establishes Quality Assurance requirements for items and services that provide a safety function. CGD process is used when items or services that provide a safety function are not provided by NQA-1 qualified suppliers.

For Example: EPRI NP-5652, EPRI TR-106439 and EPRI TR-102260 – EPRI NP-5652, Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications; EPRI TR-106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Application; and EPRI TR-102260, Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items are recognized in the nuclear industry as the standard documents regarding the purchase of commercial grade items for use in nuclear related applications.

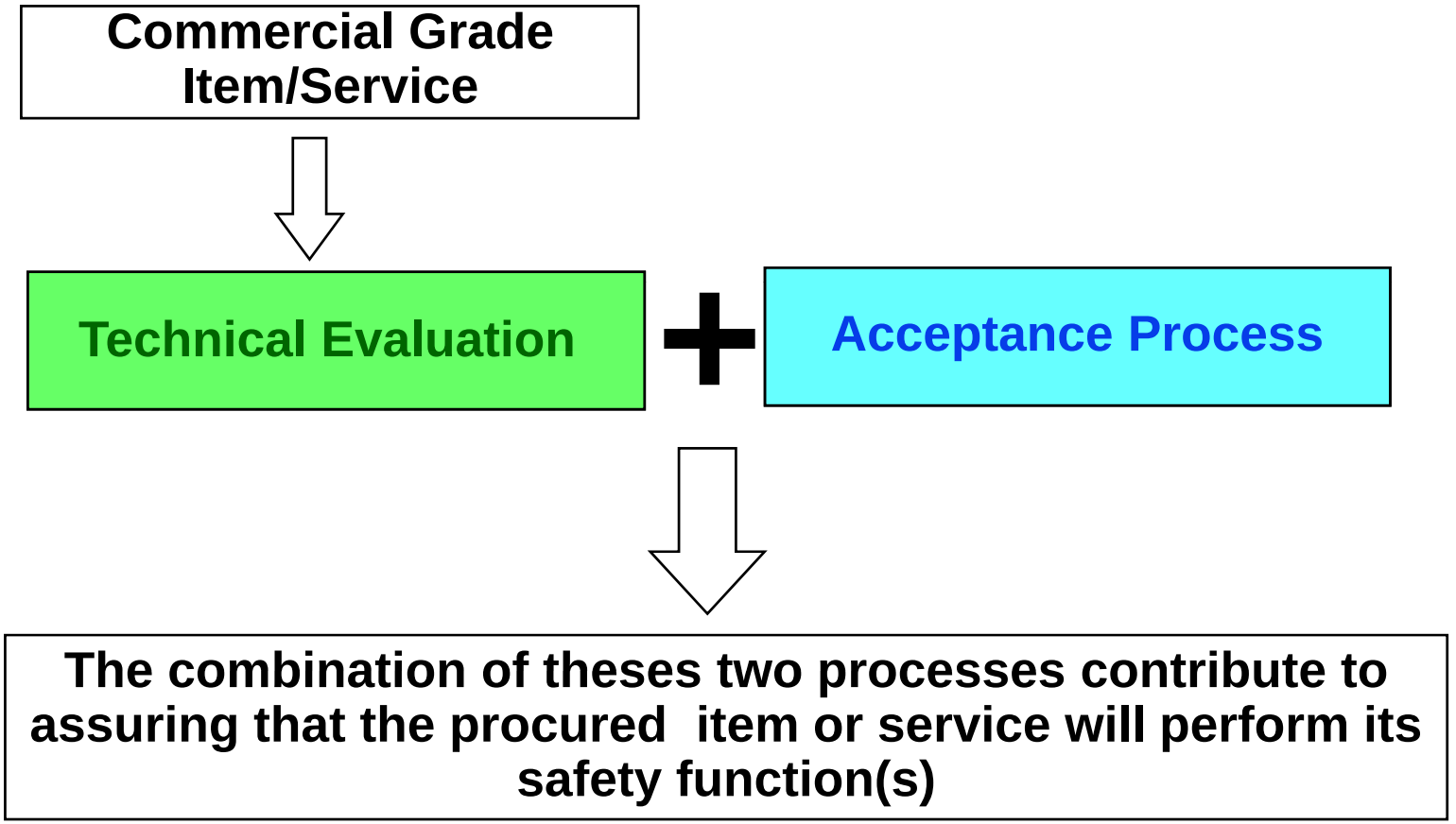
Major Steps In The CGD Process

- Clearly identify the item – Bound the application
- Determine if the CGD is Like-for-Like or Equivalent
- Research the design to identify the safety functions, the service conditions and the design margin
- Determine the safety significance of the item considering the consequences and likelihood of failure

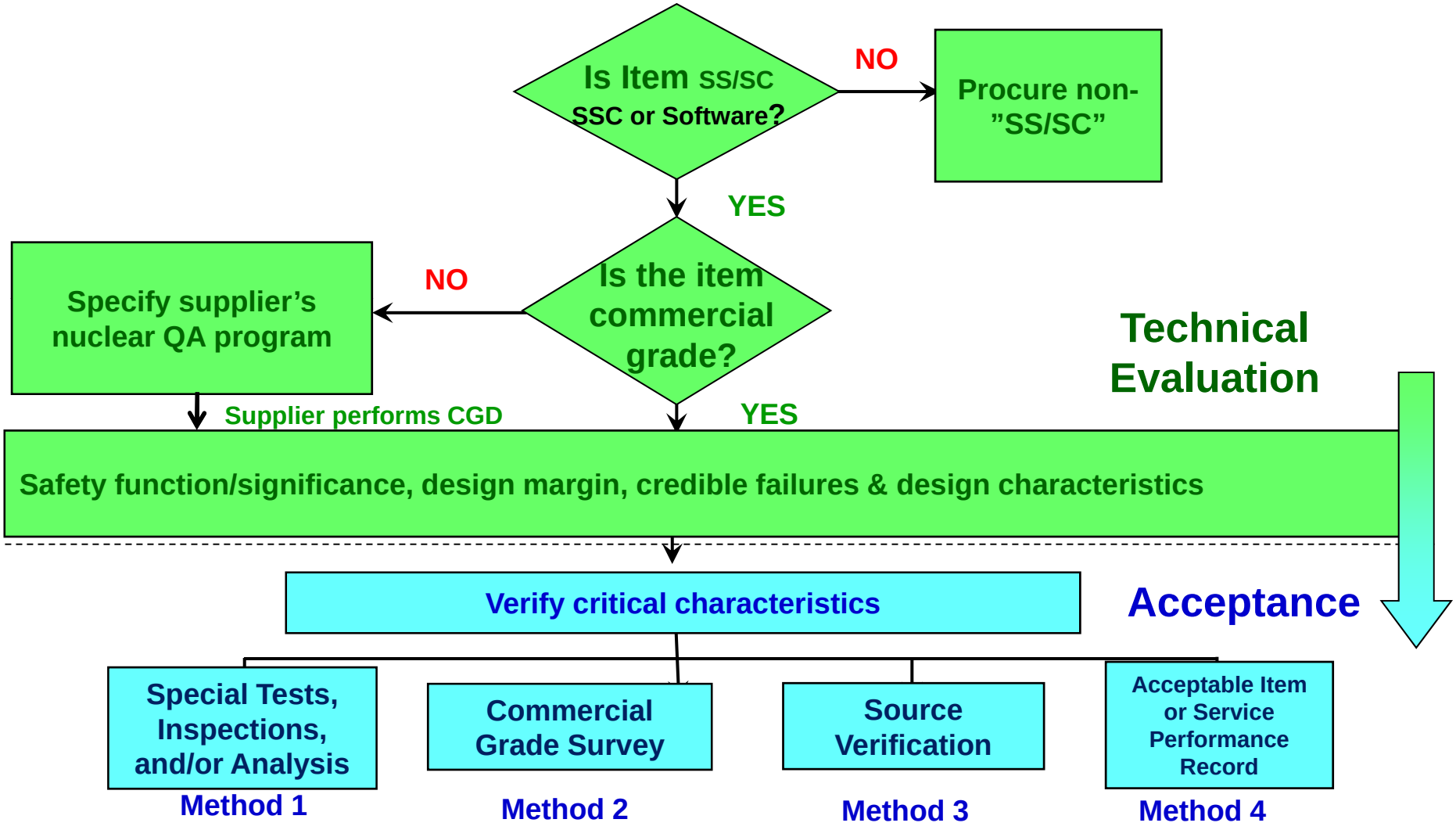
Major Steps In The CGD Process (cont.)

- Determine the characteristics of the item that are critical to performance of the safety function
- Select acceptance methods, acceptance values and sample plans commensurate with the items significance
- Document approval that the item/service will, “with reasonable assurance” perform its safety function
- Document the basis

Commercial Grade Procurement Fundamentals



Overview of the Generic Process



Quality Level Determination

- Determination of item safety function is part of the design process
- Safety functions are reflected in specifications, drawings, data sheets, procurement packages, Preliminary Hazards Analysis, Hazards Analysis, safety basis documents (e.g. Documented Safety Analysis), and in DOE Safety Evaluation Reports.
- Technical justification should be documented for items classified differently than their host system/component
- Quality level of a service is equivalent to the quality level of the items associated with the service

Determine if the Item or Service Meets the "Commercial Grade" Definition

- NQA-1a-2009 provides three definitions for a commercial grade item depending on the application of the item.
- Definition 3:
  - Commercial Grade Item (CGI) is a structure, system or component (safety-class/safety-significant), or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of this Standard (NQA-1a-2009)
  - Commercial Grade Service (CGS) is a service that is not provided by an NQA-1 qualified supplier

Utilization of the CGD Process

- Utilization of the CGD process for procuring items or services includes the following:
  - Technical evaluation to determine that the item or service performs a safety function
  - Confirmation that the item or service meets the commercial grade definition criteria
  - Identification of the critical characteristics and acceptance criteria
  - Selection, performance, acceptance, and documentation of the basis for the acceptance requirements

Utilization of the CGD Process (cont.)

- Items or services that successfully complete the dedication process are subject to the controls of Part I and II of NQA-1
- The Buyer can consider industry standards to meet NQA-1 requirements such as using an American Society of Mechanical Engineers (ASME) certificate holder or a Underwriters Laboratory (UL) listing.

Identify Critical Characteristics

Safety functions of the item

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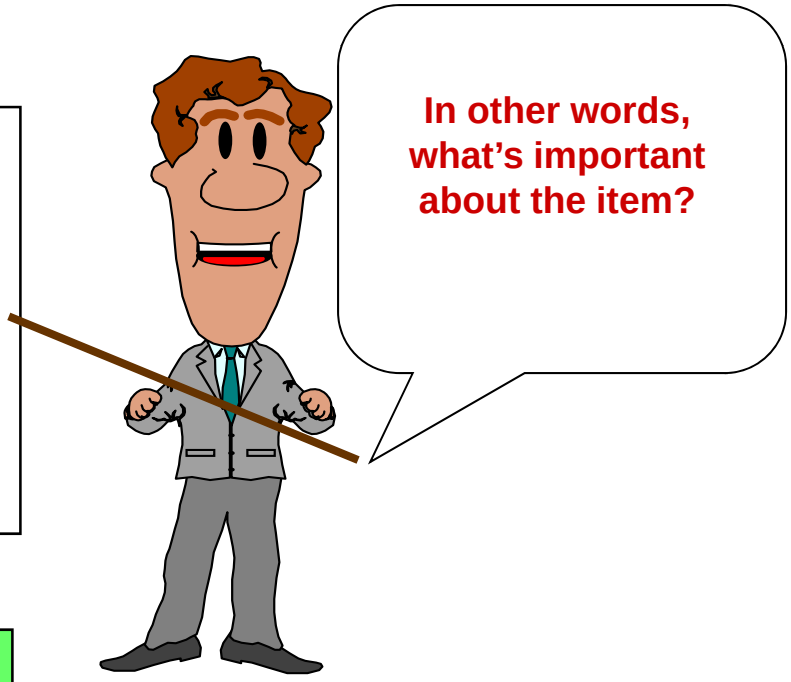
Postulated credible failures of the item

What physical or performance attributes of the item enable it to perform design functions related to the safety function or prevent it from failing as postulated?

Critical characteristics

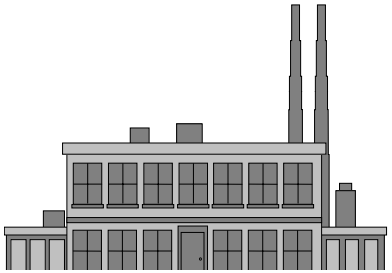


When Critical Characteristics Are Verified

Prior to or During Manufacturing at Supplier/Sub-Supplier

During or After Receiving

After Installation



Receipt of Raw Material

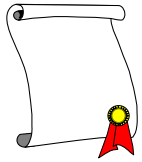
(Method 1)

Source Survey

(Method 2)

Source Verification

(Method 3)



Review of supplier documentation

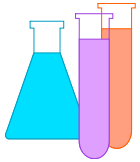
(Method 1)

Inspection of the item

(Method 1)

Post installation testing of the item

(Method 1)



Testing of the item

(Method 1)

CGD Summary

- CGD is an acceptance process performed in accordance with procedures to provide reasonable assurance that a CGI or CGS will successfully perform its intended safety function.
- Commercial grade dedication consists of two processes:
  - Technical evaluation – assures that the requirements for an item/service are specified in procurement documents
  - Acceptance process – provides methods to reasonably assure that the item/service received is what was specified

CGD Summary (cont.)

- CGD is deemed equivalent to an item or service provided from a qualified NQA-1 supplier
- Dedication can be performed by the Prime Contractor, a qualified NQA-1 supplier, or a NQA-1 qualified third-party dedicating entity in accordance with their approved NQA-1 Program
- Dedication performed by a qualified NQA-1 Supplier or a third-party dedicator must be performed in accordance with a Buyer accepted CGD program.

CGD Summary (cont.)

- Dedication plans and records from suppliers/dedicators should be obtained as part of the record set when the supplier/dedicator is the Dedicating Entity.
- Dedication is complete when the organization verifying the critical characteristics completes the acceptance activities

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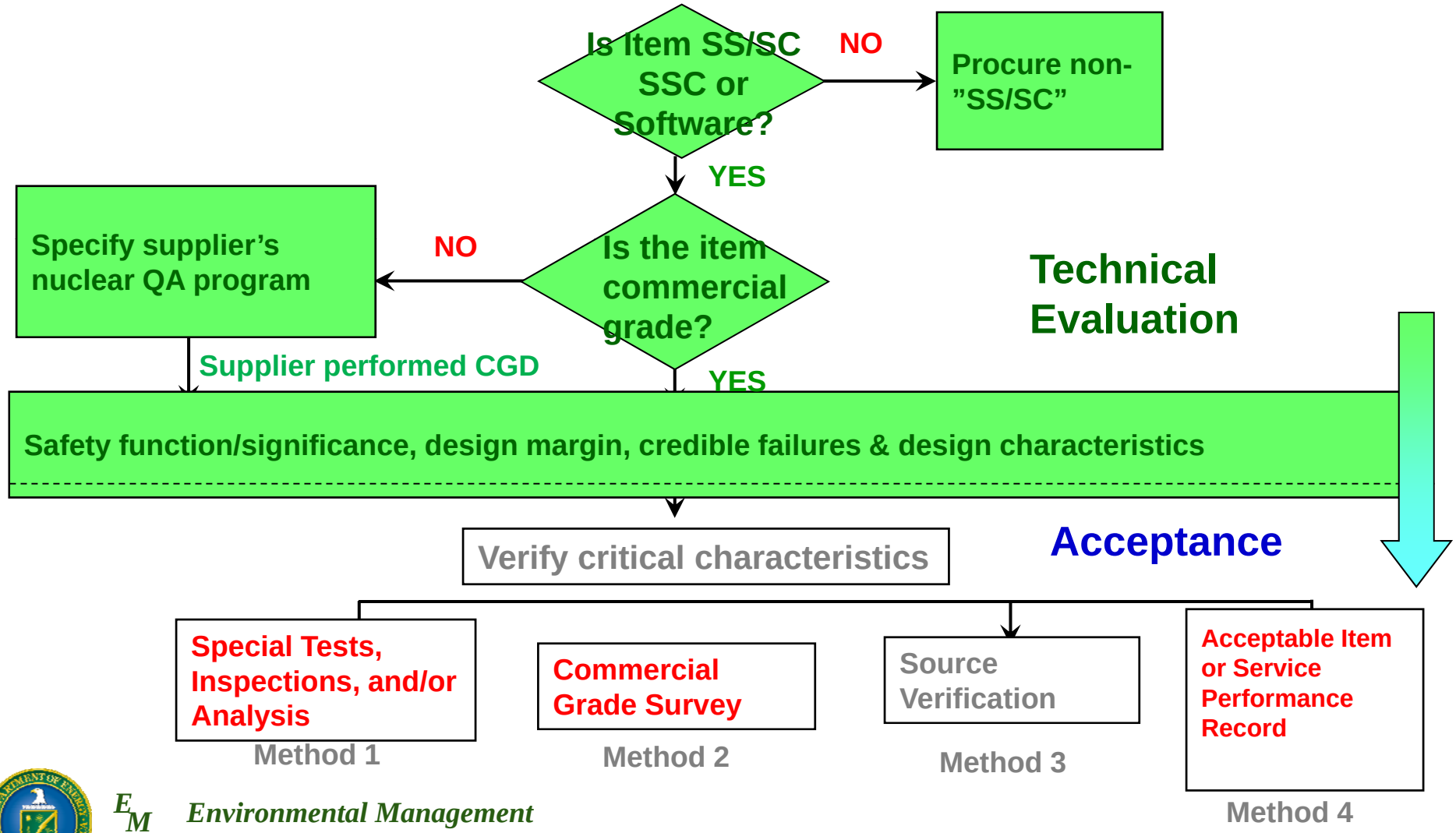
MODULE 2

Technical Evaluation

Enabling Objectives

- Describe the purpose of the technical evaluation
- Describe the steps in performing the technical evaluation
- Describe the thought process for determining critical characteristics of design for items and services

Overview of the Technical Evaluation



Purpose of the Technical Evaluation

- Enable the item/service to be specified correctly in a procurement document
- The evaluation shall be performed by the responsible Engineering organization:
  - Determine the safety function(s) of the item or service
  - Identify performance requirements, the component/part functional classification, and applicable service conditions
  - Identify Design Requirements

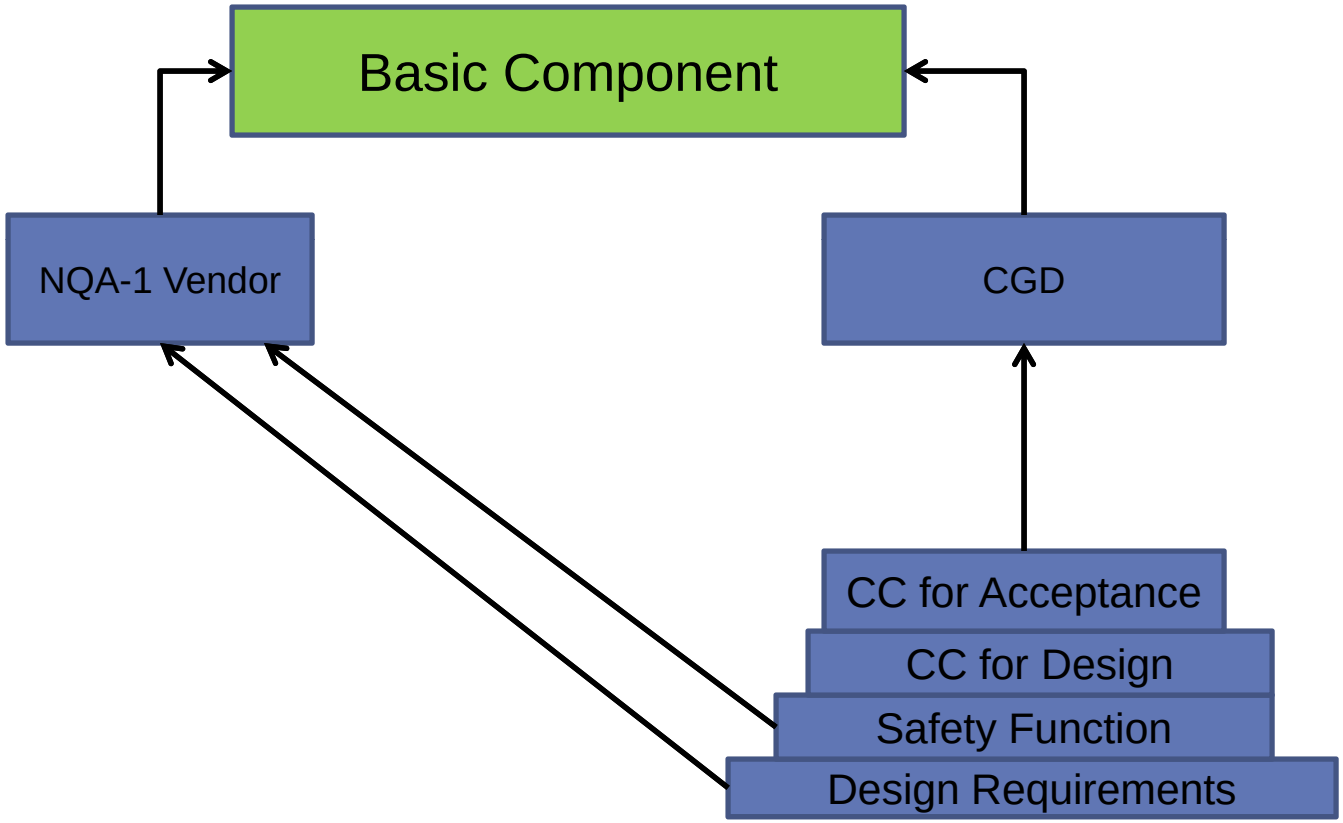
Purpose of the Technical Evaluation (cont.)

- The evaluation shall be performed by the responsible Engineering organization (cont.):
  - Confirm Item meets Commercial Grade Definition
  - Understanding of end-use application(s) including the most severe location of the item or the item impacted by the service
  - Identify Critical Characteristics, including acceptance criteria
  - Identify the dedication method(s) for verification of the acceptance criteria

Basic Components

- A basic component is a structure, system, or component (SSC) or part thereof that affects its safety function, that was designed and manufactured in accordance with the requirements of this Standard (NQA-1a-2009), or commercial grade items which have successfully completed the dedication process.
  - Basic Components are those that have been shown to have adequate assurance that they will perform their intended safety functions on demand.

Technical Evaluation Supporting a Basic Component



Other Input for Consideration in the CGD Process

- ASME Certificate Holder
  - When a procurement specifies that material be fabricated to ASME Section III, then an ASME National Pipe Thread (NPT) stamp-holder can qualify material under NCA 3855.5 (i.e., use of unqualified source material) instead of CGD
  - An ASME Material Organization using (unqualified source material (non-NQA-1 material) in an NQA-1 application supporting a non-ASME Section III procurement, must perform CGD on that material
  - If the buyer's QA program allows ASME Section III, 3800 as a consensus standard then the Material Organization can follow 3855.5 to upgrade the unqualified source material for their NQA-1 application

Other Input for Consideration in the CGD Process (cont.)

- The Buyer must verify the implementation of the fabricator's QA program that supports the use of the ASME Certificate. Examples include:
  - Use of Inspection/Test by reviewing the method of verifying material used to validate the Fabricator or Supplier's Certified Material Test Report (CMTR)
  - Performance of chemical and physical tests at a qualified laboratory
  - QA inspectors can perform inspections on site when appropriate
  - A survey to review applicable portions of the Fabricator's program to support the test.
  - A source verification of specific activities to verify appropriate QA is implemented during fabrication/development.

Other Input for Consideration in the CGD Process (cont.)

- UL Listing
  - When a procurement specifies that an item meet UL requirements, than the presence of a UL label can be listed as a critical characteristic for acceptance (CCFA)
  - The supplier's UL testing program must cover the CCFAs for the specific application for the UL equivalency.
  - The supplier's procedures must implement the appropriate testing
  - The purchaser must verify that the manufacturer has a UL testing program that applied the UL label and that adequately addresses the CCFAs for the component.

Like-For-Like Determination

- The term like-for-like was used in EPRI Report NP-5652 and EPRI Report NP-6406 to describe a procurement scenario in which a minimal technical evaluation is required for a replacement item.
- NQA-1 defines like-for-like replacement as the replacement of an item with an item that is identical. It further defines “identical item” as an item that exhibits the same technical and physical characteristics (physically identical).

Like-For-Like Determination (cont.)

- If the design, materials, manufacturing processes, and end use of an item are identical to an item or service that has already been accepted and CGD performance issues have not been identified for that item, then NQA-1 states that no further technical evaluation is required.
- The item must still meet CCFA established by the initial CGD plan.

Like-For-Like Determination (cont.)

- Considerations for achieving a high confidence that the replacement is identical to the original or to establish the degree of engineering evaluation deemed necessary:
  - Same Manufacturer
  - Complexity of the item
  - Same published product description of the item
  - Supplier performance
  - Adequate supplier design change process to ensure no changes have been made to the design
  - Adequate supplier controls of the manufacturing and procurement process
  - Supplier reaffirms no changes in material, design, physical characteristics (fit, form), function or inter changeability

Like-For-Like Determination (cont.)

- Items may be considered identical or like-for-like if one of the following applies:
  - The item is provided from the original equipment manufacturer (successor companies that maintain equivalent quality controls are acceptable), and has not been subject to design, materials, manufacturing, or nomenclature changes.
  - The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification.
  - Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item.

Equivalent Items

- When difference(s) exist from the original item, an equivalency evaluation is required to determine if any changes in design, material, manufacturing process, form, fit, or function could prevent the replacement item from being interchangeable under the design condition of the original items and performing its required safety function.

Equivalent Items (cont.)

- The equivalency evaluation shall be documented and include the following:
  - Identification of the change(s) in design, material, manufacturing process, software development process, configuration, form, fit, or function of the replacement item that is different from the original item
  - Evaluation of the change(s)
  - Confirmation that the changes(s) does not adversely affect the current design or safety function of the item

Equivalent Items (cont.)

- If the change(s) adversely affects or is not bounded by the current approved design bases, the replacement item is not equivalent and must be rejected or processed as a design change in accordance with Part 1, Requirement 3, section 600, “Change Control”.
- Equivalency can be used for software when the computer instructions associated with the safety function and any of the safety functions' interfaces are not changed. This allows for independent non-safety functions to change or software tools that assist in the creation of the software item (e.g., compilers) to be changed.

Equivalent Items (cont.)

- Equivalency evaluations can determine the acceptability of the difference in the item to perform its safety function and identify critical characteristics for acceptance for the replacement item.
- Equivalency evaluations are not to be used as the sole basis to accept a commercial grade item.
- Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

Safety Function and Safety Classification

- The need for CGI dedication is not solely a result of safety designation, but may also be a result of repository waste affecting items designation and Air Permit functions that are part of an emission unit that meets the requirements of Stated Codes.
- The safety function or functions of item are determined during hazard and accident analysis during the development of the safety basis.
- Safety functions are assigned by the approved safety basis based on DOE-mandated requirements and guidelines to prevent/mitigate release of radiological/chemical materials.

Safety Function and Safety Classification (cont.)

- Output of the development of the safety basis is a set of Safety Class (SC) and Safety Significant (SS) structures, systems, and components (SSC) designed to protect the facility workers and public from excess radiation and chemical hazard doses.
- Engineering evaluates CGI dedication services to determine if the service could adversely affect the safety function of an item

Critical Characteristics

- ASME NQA-1a-2009, subpart 2.14, defines a critical characteristic as,
  - "important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function"

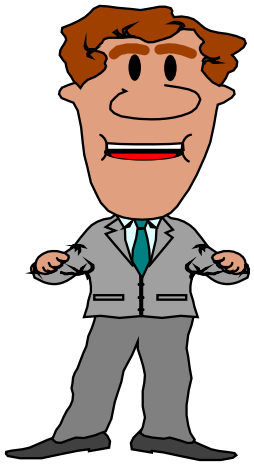
Reasonable Assurance

- EPRI TR-102260, Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items, defines reasonable assurance as;
  - A justifiable level of confidence based on objective and measurable facts, actions, or observations which infer adequacy.
- NQA-1a-2009 states,
  - The dedication activities are intended to provide reasonable assurance that the item or service will perform its intended safety function.

Recommended Process for Identifying Safety Function & Determining Critical Characteristics

Thought Process

Research design documents and databases to determine system and component level safety functions. Part level safety functions must be deduced from this information



Perform a search of the Design Documents and Design Criteria Databases

Typical Safety Functions

- Typical Mechanical Safety Functions
  - Maintain pressure integrity
  - To open
  - To remain open
  - To close/isolate
  - To actuate/modulate flow
- Typical Electrical Safety Functions
  - Electrical isolation
  - Provide signal or power

Recommended Process for Identifying Safety Function & Determining Critical Characteristics

Thought Process

What are the safety function(s) of the item/service?

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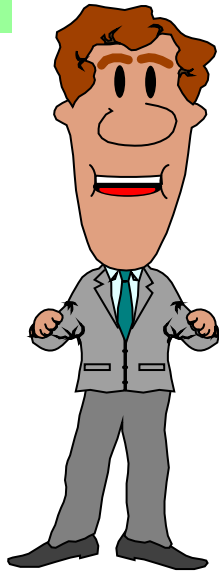
What are the facility design function(s) (including known safety functions and seismic/environmental conditions) of the item/service?

This information should be obtained from the appropriate design documents!



Recommended Process for Identifying Safety Function & Determining Critical Characteristics

Thought Process

What are the safety function(s) of the item/service?

↓

What are the facility design function(s) (including known safety functions and seismic/environmental conditions) of the item/service?

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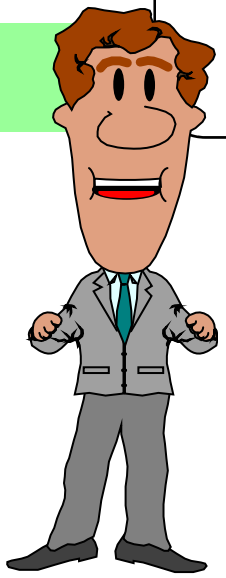
What are the postulated, credible failure mechanisms of the item/service?

Hypothetically, how could this item/service fail during normal *and* accident conditions?



Credible Failure Mechanisms

- The credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function shall be considered in the technical evaluation (TE) for the selection of CC
- Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations
- The basis for determining that specific failure mechanisms are not credible should be documented

Credible Failure Mechanisms (cont.)

- Once the safety functions are determined, the selection of critical characteristics begins
- Failure of some important design features of an item may not be credible, with no need to be verified.
- Considerations in mechanical and electrical applications.
  - Fracture
  - Corrosion
  - Erosion
  - Loss of properties
  - Excess strain
  - Mechanical creep
  - Ductile fracture

Potential Failures in the Performance of Services

- Repair Services – use of unacceptable parts, improper welding or soldering, improper assembly, component requirements not met after repair
- Testing – use of uncalibrated equipment, technical inadequacies in performing the test, improper specimen preparation, improper calculation of test results
- Fabrication/Machining/Cleaning/Unique Manufacturing Processes – failure to meet dimensional requirements, material contamination, special process controls

Potential Failures in the Performance of Services (cont.)

- Training – errors in instructional materials used
- Engineering/Technical Services – calculation errors, unconfirmed assumptions, unconfirmed/unverified computer codes to perform analyses/calculations
- Calibration – equipment out of calibration causing failure to accurately measure or actuate at the proper time, incorrect equipment calibration

Postulating Failures

- Consider single-failure analysis
  - Redundancy in design should not be considered as a means to mitigate a failure
- Postulate failures based upon the safety functions of the host component, considering normal and accident design bases.
- Do not consider the following as credible failures :
  - Normal wear-out (over a long period of time)
  - Failure due to improper maintenance
  - Failure due to improper installation
  - Failure caused by failure of adjacent items

Recommended Process for Identifying Safety Function & Determining Critical Characteristics

Thought Process

What are the safety function(s) of the host SC/SS component?

↓

What are the facility design function(s) (including known safety functions and seismic/environmental conditions) of the item/service?

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What are the postulated, credible failure mechanisms of the item/service?

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Will failure mechanisms(s) adversely affect component/system safety function(s)?

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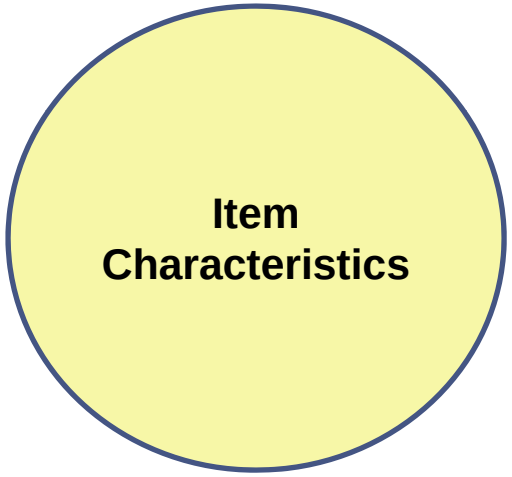
Item Characteristics



- Characteristics Including Product Identification Characteristics
- Other characteristics that are inherent to the item's design but are not required/used in the purchaser's application to support the safety function.

Recommended Process for Determining Design Characteristics

What are the safety function(s) of the item system/component?

↓

What are the facility design function(s) (including known safety functions and seismic/environmental conditions) of the item?

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What are the postulated, credible failure mechanisms of the item?

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What identifiable and measurable attributes are essential for the item's form, fit, and functional performance?

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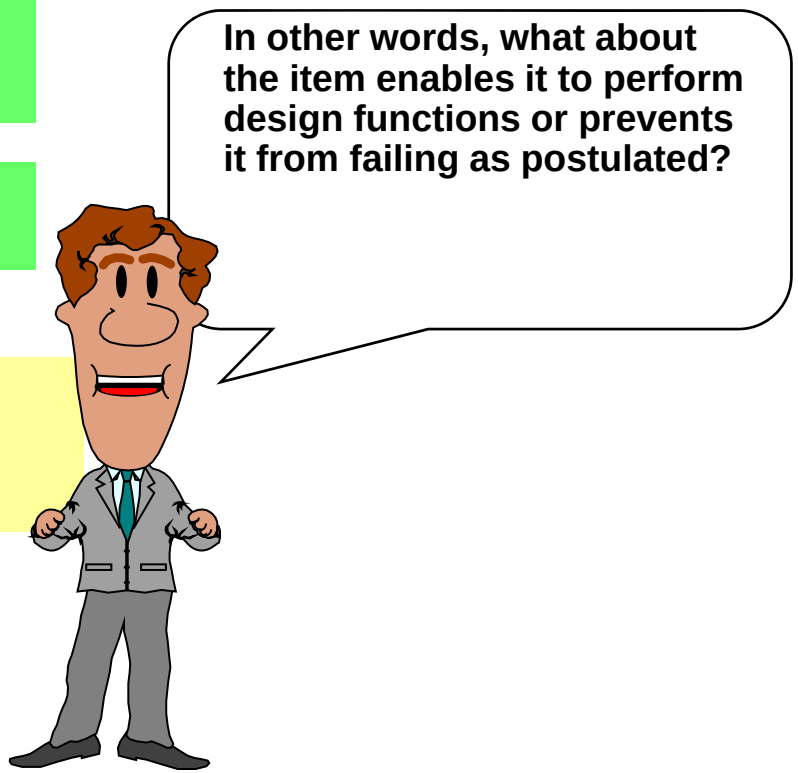
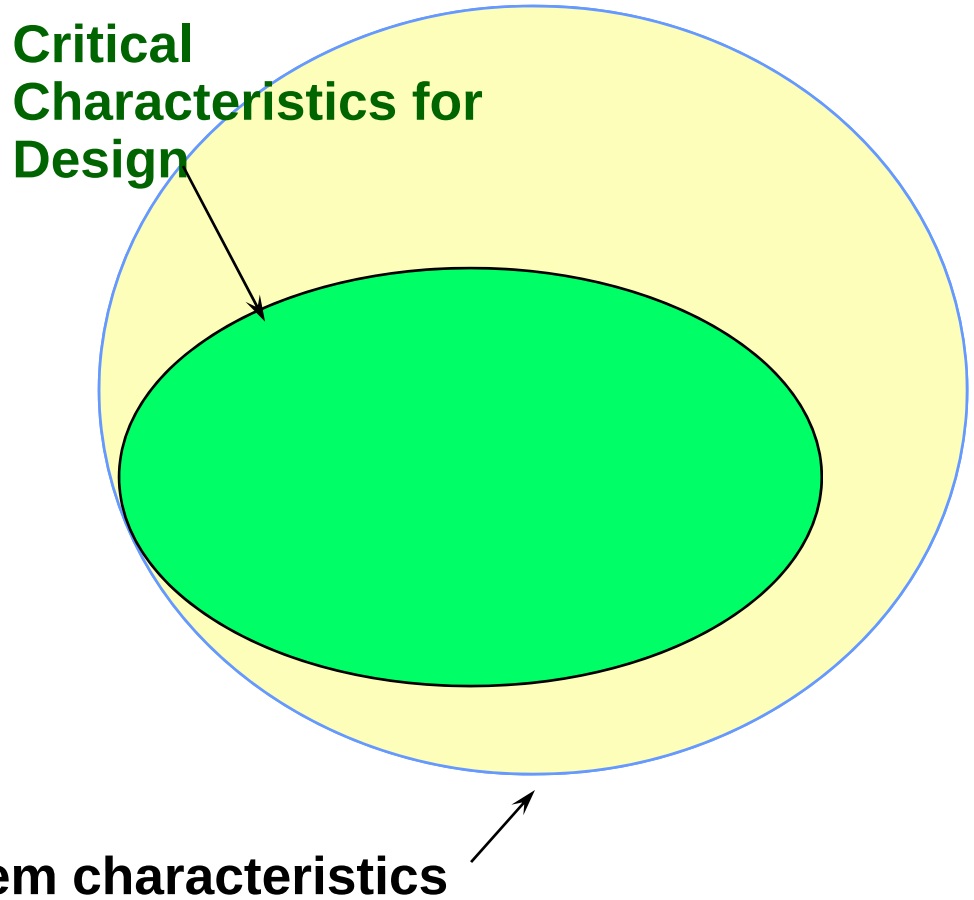
Design Characteristics



Critical Characteristics for Design



- Dependent on the facility-specific application
- Are a subset of the entire population of attributes describing an item
- Are based on the item's safety functions
- Are application specific and include physical and performance characteristics
- Include design, material and performance attributes of the item

Critical Characteristics for Design (cont.)

- If the design criteria for the commercial grade item are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific safety function. This might be most appropriate for commodity items.
- In this case, consideration of failure modes is not required and the item's design parameters and allowables become the critical characteristics and acceptance criteria

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Commercial Grade Dedication Training

MODULE 3

Acceptance Planning

Enabling Objectives

- Describe the thought process for determining critical characteristics for items and services
- Understand the concept of “reasonable assurance” commensurate with the significance of the safety function
- Describe the different types of critical characteristics
- Describe the processes for acceptance of services
- Describe how to achieve reasonable assurance in the context of commercial grade item dedication

Critical Characteristics of an Item or Service

- Critical Characteristics defined in NQA-1a-2009
  - Important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.
- Critical Characteristics for Design – EPRI NP-6406
  - Critical characteristics include physical and performance characteristics of the item but not product identification characteristics
- Critical Characteristics for Acceptance – EPRI 102260
  - Critical characteristics for acceptance are generally a subset of the critical characteristics for design but can include physical characteristics of an item, identification marking, or performance characteristics of the item (refer to slide 61)

Recommended Process for Determining Critical Characteristics

What are the safety function(s) of the host component?

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What are the facility-specific safety function(s) of the item?

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What are the postulated, credible failure mechanisms of the item that potentially affect the safety function?

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What identifiable and measurable attributes enable the item to perform its safety function(s)?

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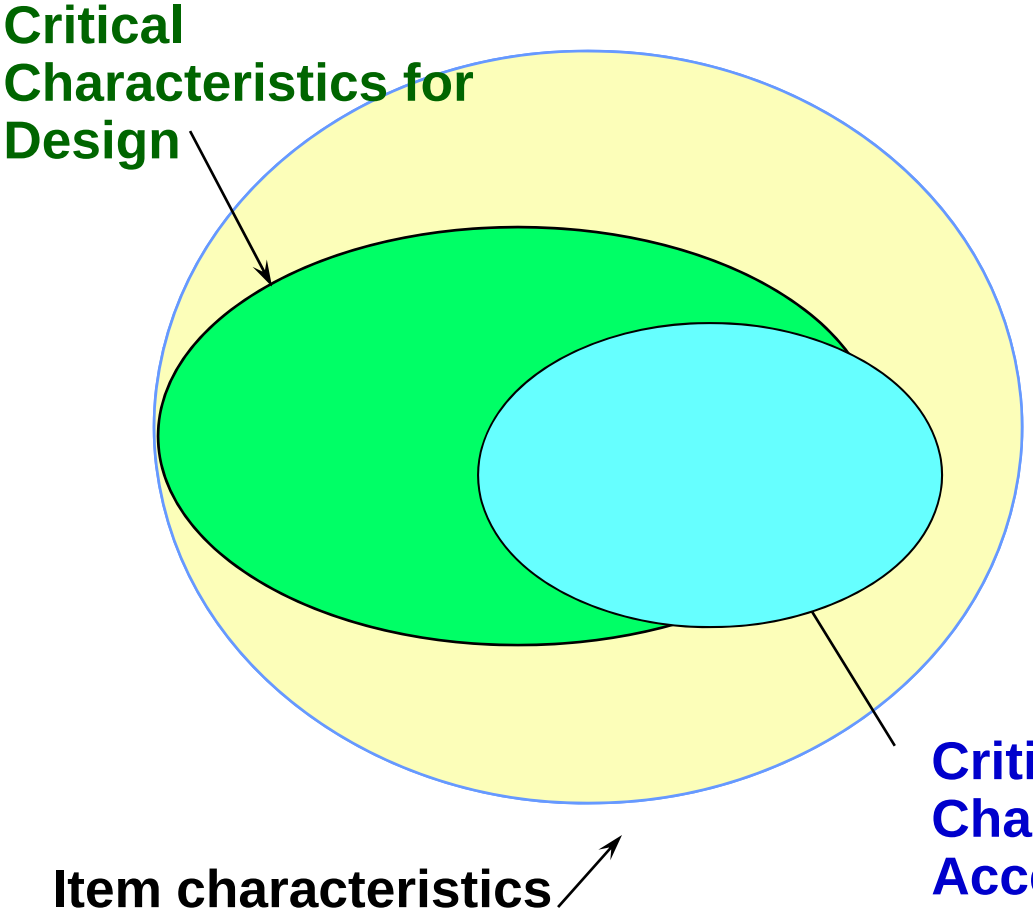
Critical Characteristics

Critical Characteristics for Acceptance



- Are based on the item's *safety* functions
- Are design, material and performance attributes of the item that support the safety function
- Are measurable and verified
- All must be verified once selected
- Shall include tolerances when appropriate

Representative Types of Critical Characteristics

- Design (Configuration) Characteristics
  - Dimensions
  - Electrical resistance
  - Durometer hardness
  - Part number if assigned
- Material (Physical) Characteristics
  - Material chemical composition
  - Material properties
    - Strength, hardness, ductility, elasticity, melting temperature, density, permeability, conductivity, etc.
- Performance Characteristics
  - Pick-up/drop-out voltage
  - Open/close time
  - Input/output voltage

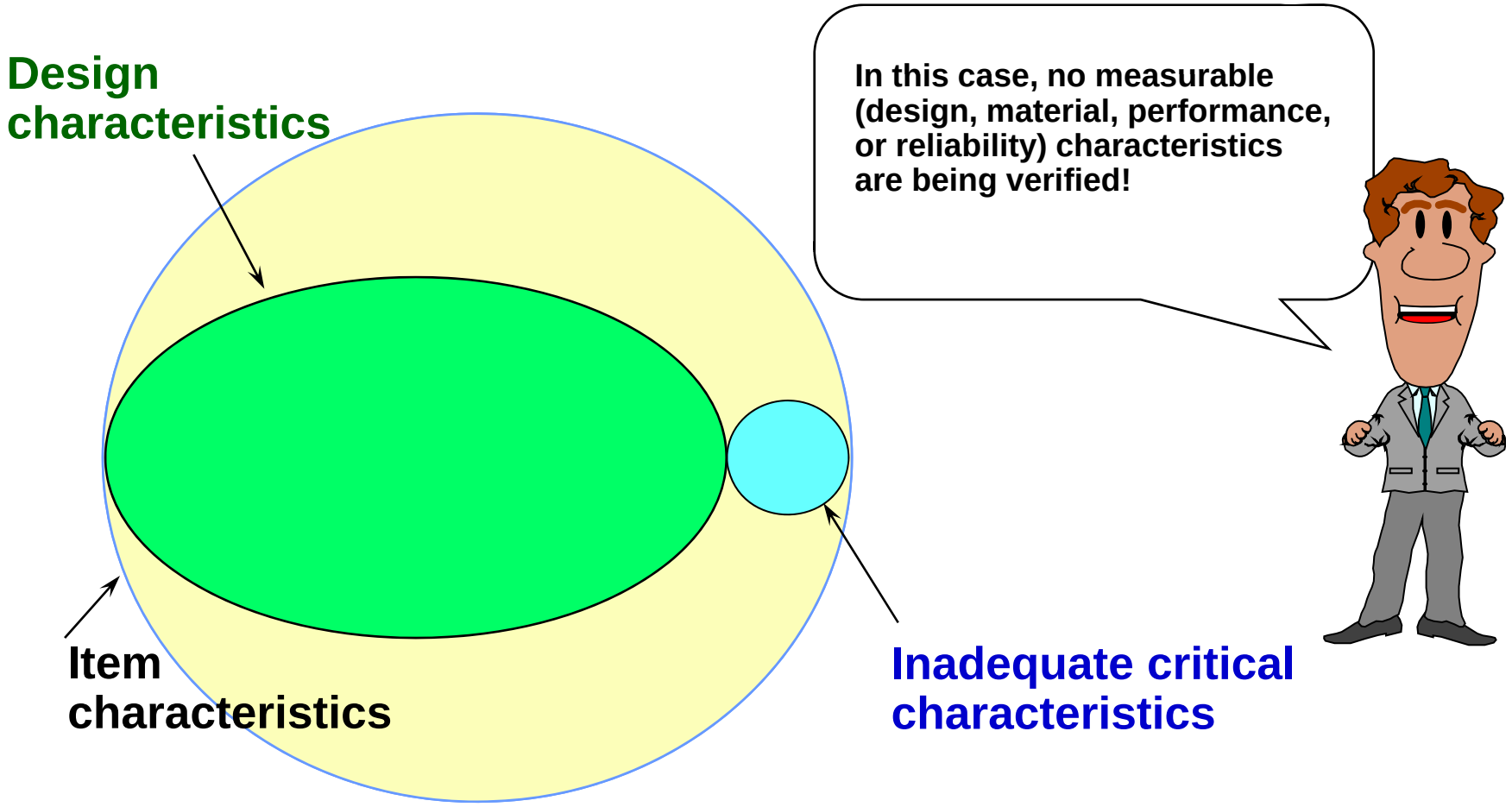
Representative Types of Critical Characteristics (cont.)

- Dependability Characteristics – Digital Equipment and Software
  - Typically cannot be verified by inspection and testing alone
  - Are generally affected by the process used to produce the device.
  - Includes reliability, safety, availability, maintainability, and built-in quality

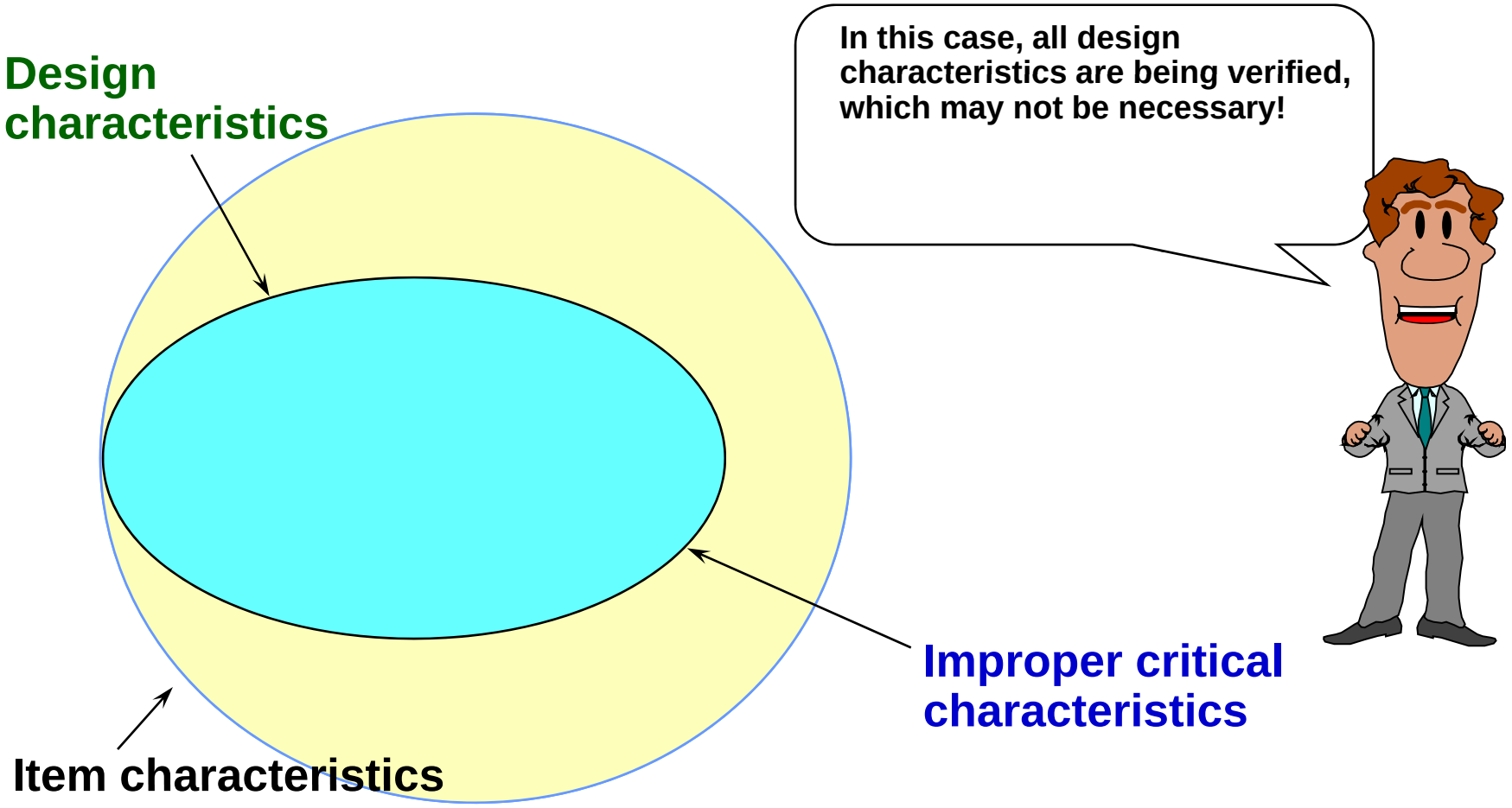
Understanding What Does Not Constitute a Critical Characteristic

- Form and fit
- Seismic Qualification
- Environmental Qualification
- Certificate of conformance
- Hydrostatic test
- Receipt inspection
- Lot homogeneity
- Commercial grade survey
- Maintenance instruction
- Environmental test report
- Vendor manual

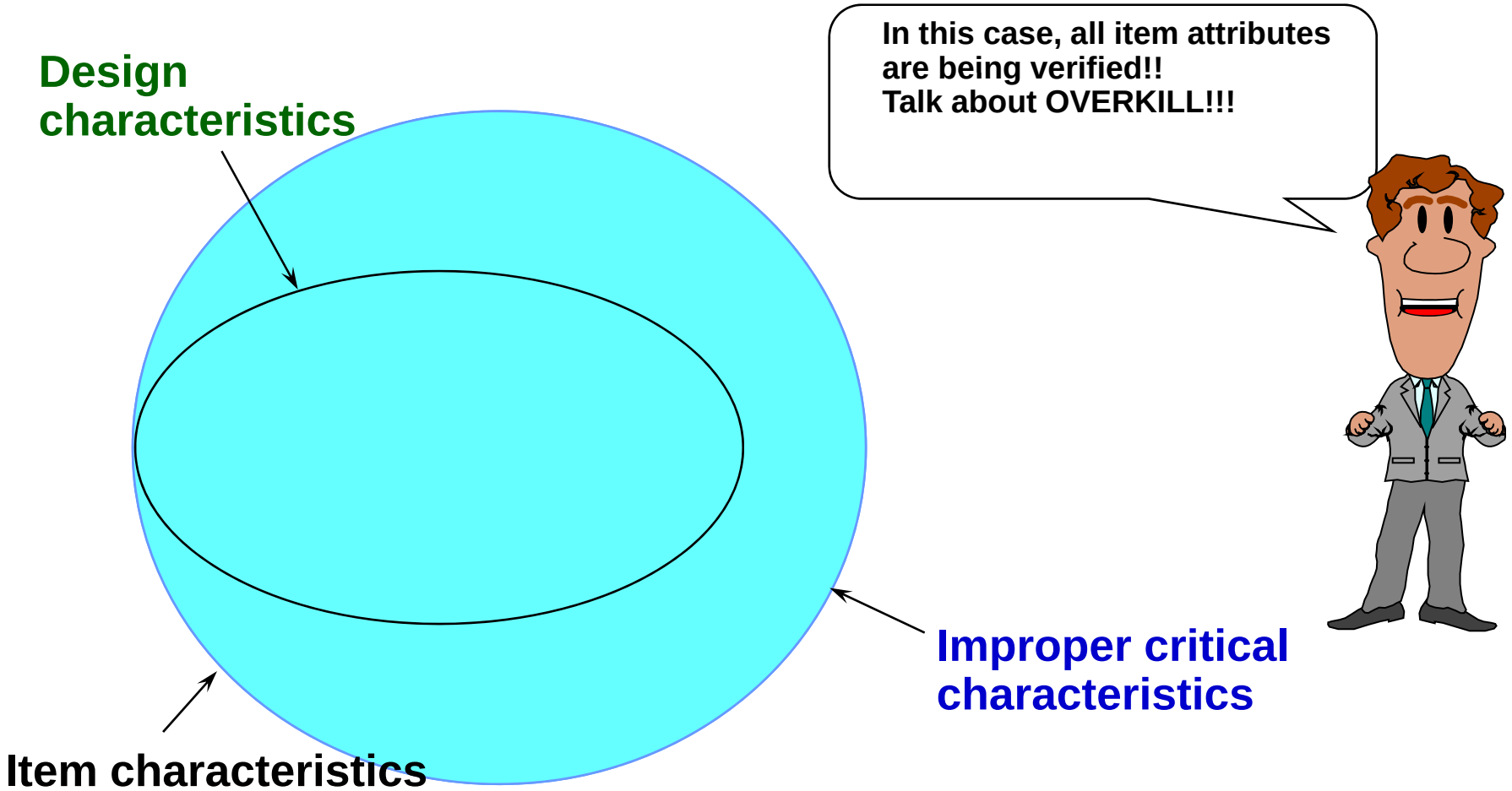
Inadequate Selection of Critical Characteristics



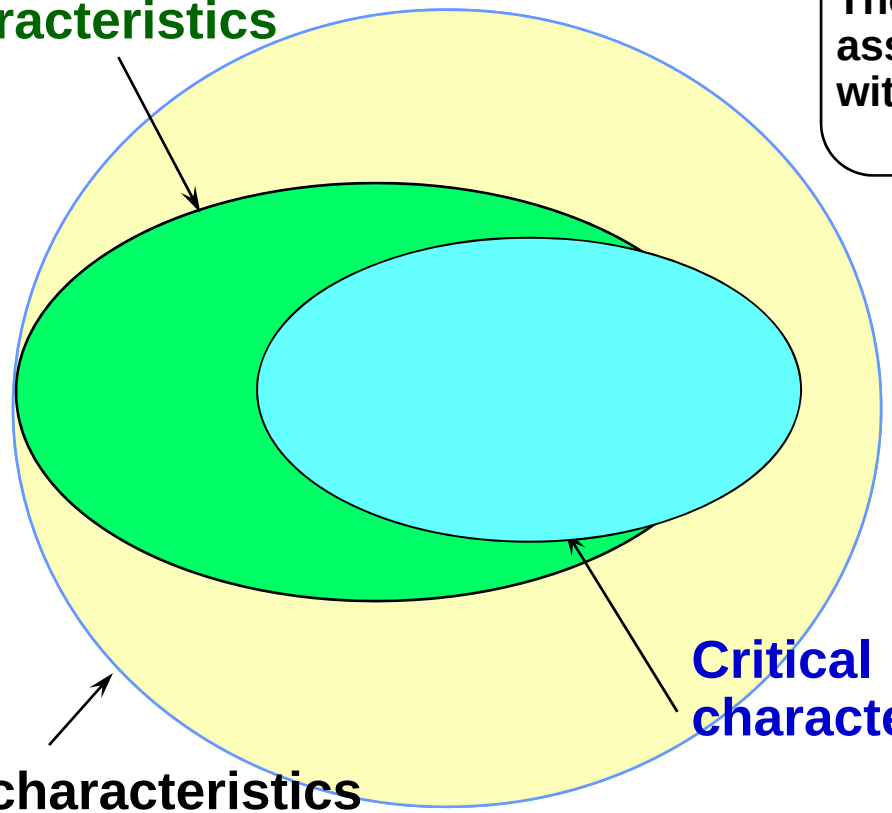
Inadequate Selection of Critical Characteristics (cont.)

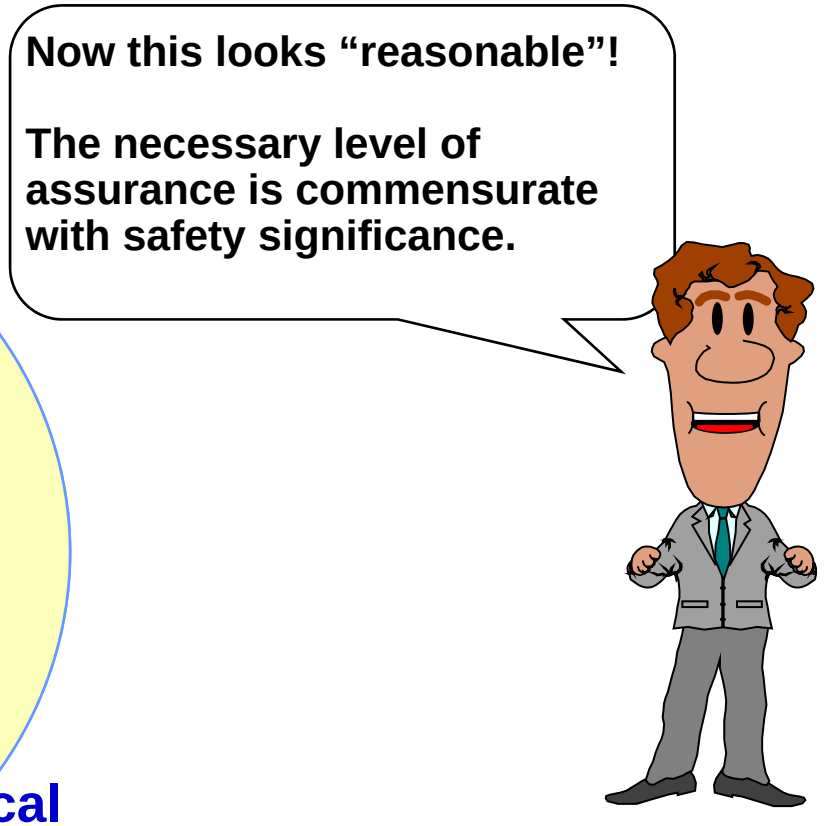


Inadequate Selection of Critical Characteristics (cont.)



Proper Selection of Critical Characteristics





Critical Characteristics for Items

- Those process controls that must be applied to ensure that the design of the item, once translated into the delivered items through manufacturing processes, will meet the requirements of the safety application in which it is to be used
- Items to be verified include:
  - Control of design inputs
  - Control of methods of analysis and design
  - Control of development, review and approval of design outputs
  - Design verification and integrated system design review

Critical Characteristics for Services

- Process for CGD evaluation for services similar to items
- Selection considerations for CC for services are:
  - Identify measurable attributes of the impacted item that affects the usability of the service AND are critical to the item performing its safety function
  - Identify in-process controls that are critical for the item impacted by the service to perform its safety function
  - Select a set of CC, that once verified, provide reasonable assurance that the service was performed properly, and the items impacted by the service perform their intended safety functions
- Note: Another option is the performance of the service under the dedicating entity's quality assurance program

Critical Characteristics for Digital Equipment and Software

- Detailed information in EPRI TR-106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications. (Oct 1996)
- Documented operating history of the equipment can be an important factor in providing confidence in the product
- Experience may be gained through applications in industries other than nuclear power

Critical Characteristics for Digital Equipment and Software (cont.)

- Experience must be shown to be relevant to the planned nuclear applications
- Additional activities such as testing will be required by the dedicator to reach an adequate level of assurance
- Additional reviews, analysis, and documentation may also be required

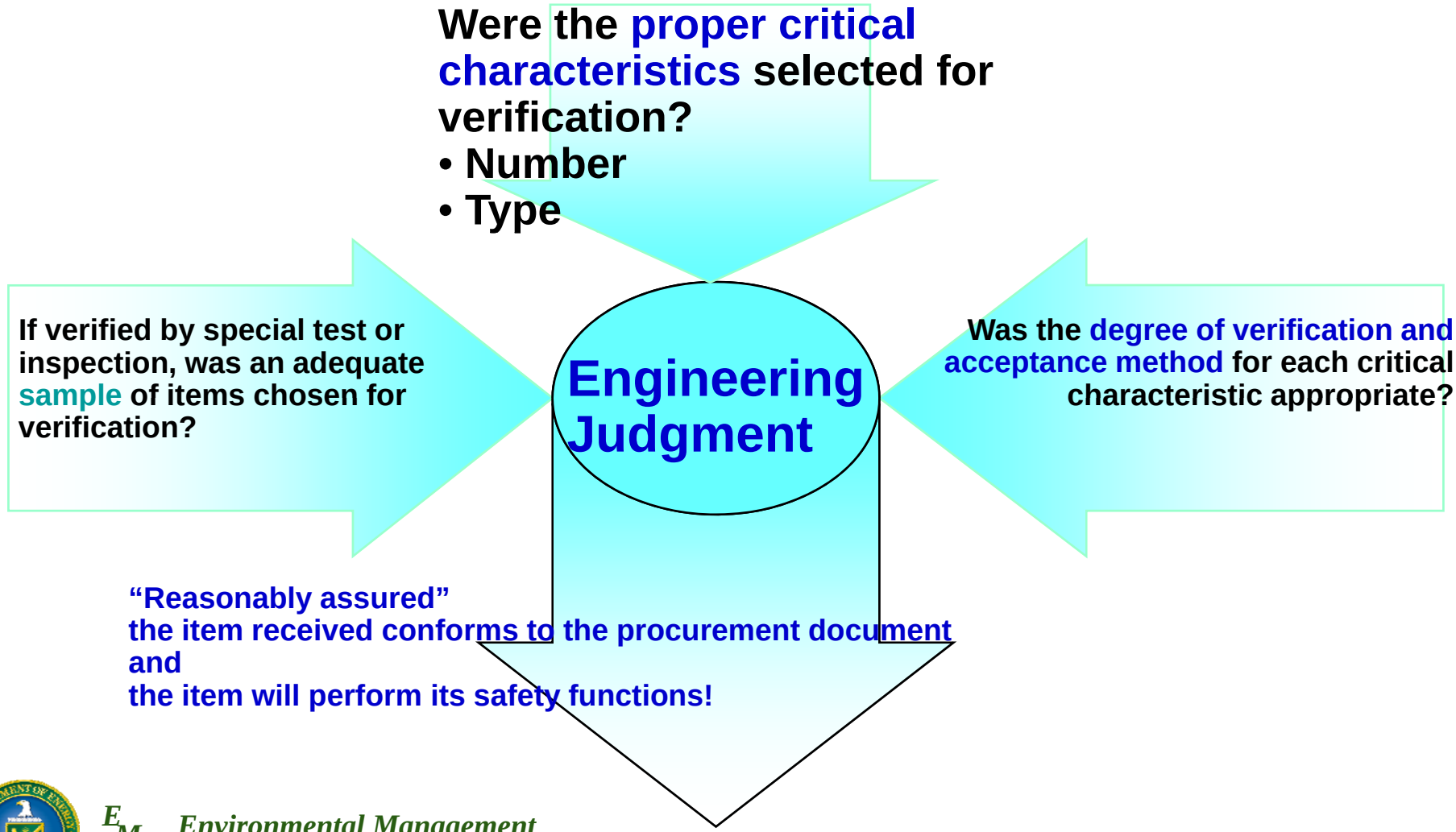
Selection of Critical Characteristics

- CGI's intended for installation in seismically or environmentally qualified applications, require CCs necessary to assure that the original qualification of the parent component is maintained.
- Environmental Qualification may deal with harsh environments or mild environments
- CGI's intended for generic safety-related applications instead of specific applications should be selected based on the most severe conditions encountered unless controls for item use are in place.

Selection of Critical Characteristics (cont.)

- The manufacture's published product description or additional technical information can be used to develop CCFA.
- The manufacturer can employ standard tests or inspections as part of the manufacturing process and utilize a quality program to assure that appropriate controls are applied.
  - In the cases where the critical CC and acceptance criteria cannot be determined from the manufacturer's documentation, the dedicating entity may perform an engineering evaluation, examination, or test (or any combination) of the original item to develop the CC's and acceptance criteria.

Achieving Reasonable Assurance in the Context of CGI Dedication



Key Elements of Critical Characteristics For Acceptance

- A listing of the selected critical characteristics
- Which method will be used to verify each critical characteristic
- The method(s) chosen:
  - Should be based on the type of critical characteristics to be verified for acceptance, available Supplier information, quality history, and degree of standardization
  - Determine when and how the critical characteristics will be verified
  - Determine what organizations will be involved in the dedication

Acceptance Methods

- Four different ways to establish CCFA for the selected critical characteristics
- Can be used individually or in combination
- Can vary from one item to another based on a number of factors such as:
  - Purchase price of the item
  - Lead times and plant schedule demands
  - Supplier capabilities and quality controls
  - Accessibility to item design information
  - Testing/inspection costs
  - Lot size

Dedication Activity

- Prior to classifying the item or service as acceptable to perform its safety function, the dedicating entity shall determine the following:
  - Damage was not sustained during shipment
  - The item or service has satisfied the specified acceptance criteria
  - Specified documentation was received and is acceptable

Dedication Activity (cont.)

- The selection of acceptance method(s) shall be planned and based on the type of critical characteristics to be verified, available supplier information, quality history, and degree of standardization.
- If a critical characteristic cannot be verified by the selected dedication method, the dedicating entity may select another or combination of dedication methods to verify the critical characteristic.

Dedicating Entity

- The dedicating entity is the organization that performs or directs the dedication activity and determines the item or service has satisfactorily met the acceptance criteria for the selected CC.
- The dedicating entity can be the manufacturer, a third-party organization, the purchaser, or the nuclear facility organization.
- The dedicating entity needs to be clearly established to all parties in the procurement.

Third Party Dedication

- EPRI TR-102260,Supplemental Guidance for the Application of EPRI Report NP-5652, provides the following guidance:
  - Any company other than the original equipment manufacturer or utility (buyer) that procures and accepts commercial grade items and supplies the dedicated items as safety-related under their approved QA program.
  - The purchase order to a third party organization (TPO) from the buyer is a safety-related purchase order.

Third Party Dedication (cont.)

- The TPO may establish a working or teaming relationship with the original equipment or part manufacturer.
  - This allows the third party organization to obtain information on design, technical requirements, and CC for design
- Buyer can provide the TPO with the technical information needed to accept the commercial grade item
- Where design information is not known, the TPO may assume item design responsibility.

Third Party Dedication (cont.)

- When the TPO is an authorized representative for a supplier and has access to the supplier's design information, the TPO may also be responsible for assuring the CGI is identical.
- If CGI is an alternate, then the TPO can be assigned to assure the item will not degrade the seismic and/or environmental qualification of the host equipment
- TPO's responsibility for like-for-like or alternate evaluations needs to be clearly specified in the contract.

DOE TRAINING

Commercial Grade Dedication Training

MODULE 4

Dedication Methods and Support Documentation

Enabling Objectives

- Describe the purpose of acceptance methods 1-4
- Describe the process for implementing acceptance methods 1-4
- Describe documentation associated with implementing acceptance methods 1-4
- Describe how performance history of the item and the supplier can affect the selection and implementation of the acceptance methods

Standard Receipt Inspection

- ANSI/ASME NQA-1 describes the standard receiving inspection as checking the following:
  - Quantity received
  - Damage
  - General condition of items
  - Part number
- Often referred to as a “kick-and-count” inspection

Would you consider this an adequate CGI dedication?

Methods for Acceptance

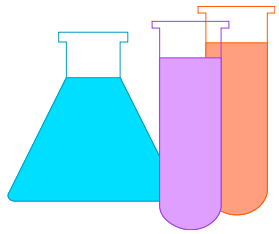
- Four methods used to accept commercial grade items/services are:
  - Method 1 – Special Tests, Inspections, or Analysis
  - Method 2 – Commercial Grade Survey of Supplier
  - Method 3 – Source Verification
  - Method 4 – History of Performance

Methods for Acceptance (cont.)

- Engineering selects the acceptance method
- Methods provide individually or in combination a means to reasonably assure:
  - Commercial grade item received meets specified requirements
  - Services provided are services ordered and the safety items affected by the service will perform their safety functions

Acceptance Method 1 - Special Tests & Inspections

- Purpose
  - To dedicate a CGI for safety-related use by verifying one or more critical characteristics using testing or inspections during and/or after receipt
- Special tests, Inspections, and analysis may be conducted prior to or during manufacturing at the supplier/sub-supplier, during or after receiving, or after installation to verify conformance with the acceptance criteria for the identified critical characteristics.



Acceptance Method 1 - Special Tests & Inspections (cont.)

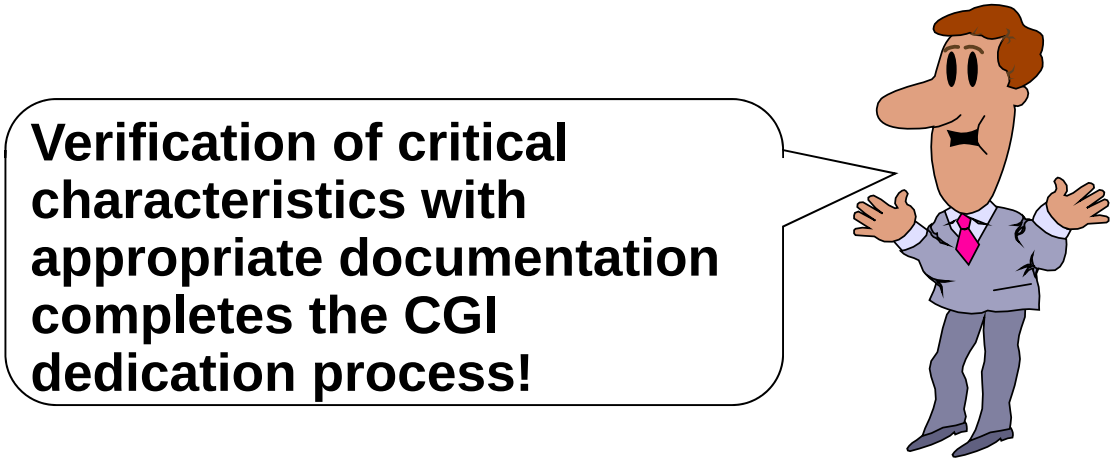
- Special tests/inspections can occur:
  - Prior to or during manufacturing at supplier/sub-supplier (e.g., raw material receipt)
  - During or after receiving of a manufactured item
  - Post installation testing (PIT)
- Sampling is permitted when testing/inspecting a batch/lot of items

Acceptance Method 1 - Guidance

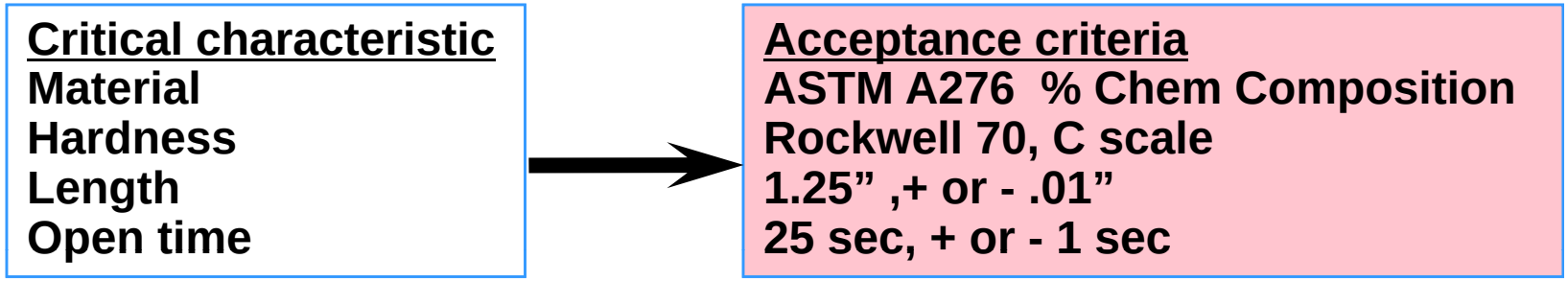
- When the item is simple in design
- Commodity items
- When critical characteristics are able to be verified with tests/inspections
- Data may be available in existing documents such as specifications, drawings, instruction manuals, bills of material and catalogs.
- Multiple suppliers of the item
- Items purchased in small quantities or larger homogeneous lots where sampling can be applied
- Items on which post-installation tests can be conducted

Standard Receipt Inspection vs. Special Tests & Inspections

- Special Tests and Inspections are one method for verifying selected critical characteristics
- These go beyond the standard receiving inspection activities
- The tests/inspections verify that the critical characteristics conform to acceptance criteria



Critical Characteristics and Acceptance Criteria



- Acceptance Criteria are generally contained in *Engineering Documents* held by the organization responsible for the design of the item. This may be the prime contractor’s engineering organization, or a supplier engineering organization, dependent on the item

Items Not Meeting Acceptance Criteria

- All values tested or inspected must fall within the tolerance range specified in the acceptance criteria
- If the acceptance criteria is NOT met, the item is documented as nonconforming
- Other like items should be evaluated to determine if they would exhibit the same nonconformance (i.e., extent of condition)
- If the CC cannot be verified by the selected dedication method, the dedicating entity may select another or combination of dedication methods to verify the CC.

Sample Size Considerations

- When sampling is required as part of the acceptance process, a key consideration is how much sampling is appropriate (discussed further in Module 5, Sample Selection Methodology)
- The logic on how the sampling size was determined needs to be documented since sampling decisions can vary from procurement to procurement.

Acceptance Method 2 - Commercial Grade Survey of Supplier

- Purpose
  - To dedicate a CGI or CGS based on approval of a suppliers' implementing process and commercial controls as related to the items CCs
- Use:
  - MUST be performed and deemed acceptable prior to procurement of a CGI or CGS
  - MUST verify that the supplier adequately controlled the CC necessary for the dedication
  - Certificates of Conformance to document surveyed controls applied and specific requirements in Procurement Documents

Acceptance Method 2 - Commercial Grade Survey of Supplier - Guidance

- When the sub-supplier/manufacturer has implemented appropriate, documented commercial controls over the critical characteristics (as verified by the commercial grade survey)
- When multiple items are being procured from the same supplier/manufacturing facility
- When those items are procured relatively frequently
- When critical characteristics are not easily verified after receipt

Practical Methodology

- Determine if a commercial grade survey has been conducted for the supplier, sub-supplier, or manufacturer
- If YES, consider the following:
  - Is the survey information current?
  - Was it conducted at the location where the CGI being procured was manufactured?
  - Does it confirm adequate supplier controls over the critical characteristics for acceptance?
  - Are the sub-supplier controls documented so they can be specified in the purchase order?

Practical Methodology (cont.)

- Determine if a commercial grade survey has been conducted for the supplier, sub-supplier, or manufacturer

- If NO, consider the following:

  - Is it cost effective to conduct a survey at this time?

  - Would other acceptance methods be more cost effective such as a source verification or special tests/inspections?

Conducting a Commercial Grade Survey

- Should be “performance-based” (not compliance-based)
- Organizations performing surveys should develop criteria for the personnel and processes used to perform surveys (e.g., including the engineering organization)
- The survey should be specific to the scope of the particular commercial grade item or service being procured
- Survey criteria should be determined by the dedicating entity

Conducting a Commercial Grade Survey (cont.)

- Survey criteria and the Supplier's documented processes and commercial controls may vary for the item or service depending on the number and type of critical characteristics to be verified.

- After a supplier's processes and controls have been determined to be adequate

  - The dedicating entity shall invoke or reference the verified processes and controls including revision level as part of the purchase order or control requirements for the CGI or CGS

  - Require the supplier to provide a certificate of conformance attesting to the implementation of the identified processes and controls.

Conducting a Commercial Grade Survey (cont.)

- "This order shall be processed in accordance with Superior Pumps Inc. Quality Assurance Manual dated 10/17/05. Any revisions to this manual shall be forwarded to the purchaser for review."
- "This order shall be processed in accordance with the following company procedures:
  - Heat treat procedure 101-63B, Rev. 2
  - Product testing procedure101-77C, Rev 0."
- "Dimensions of valve stem, Part No. XYZ123, shall be controlled in accordance with Erie Valve Inc. Machining & In-process Testing Procedure A754, Rev. 1."

Conducting a Commercial Grade Survey (cont.)

- A commercial grade survey is performed in accordance with a checklist or plan at the supplier's facility and includes or addresses the following:
  - Identification of the item(s), or product line, or service included within the scope of the survey
  - Identification of the CC to be controlled by the supplier
  - Verification that the supplier's processes and quality program controls are effectively implemented for control of the CC
  - Identification of the survey methods or verification activities performed with results obtained.
  - Documentation of the adequacy of the supplier's processes and controls.

Conducting a Commercial Grade Survey (cont.)

- Not employed as a method for accepting items or services from suppliers with undocumented quality programs or with programs that do not effectively implement the supplier's specified processes/controls.
- Not employed as a method for accepting items from a distributor unless the survey includes the manufacturer and confirms adequate processes and controls by both the distributor and the manufacturer.
- When several items or services are purchased from a single supplier, a survey of representative groups of CGI or CGS can be sufficient to demonstrate adequate processes and controls exist.

Conducting a Commercial Grade Survey (cont.)

- Surveys need to be maintained up to date and procurements should require you be notified of any changes to the programs evaluated.
- If the scope of the survey cannot verify a designated critical characteristic due to controls by the supplier's sub-supplier(s), the dedicating entity shall extend the survey to the sub-supplier(s) or select another dedication method(s) to verify the CC
- Organizations performing surveys shall develop criteria for the personnel qualifications and processes used to perform surveys.

Conducting a Commercial Grade Survey (cont.)

- The survey documentation shall provide objective evidence that the processes and controls for the identified CC were observed and evaluated for acceptance
- Deficiencies identified in the supplier's process or controls shall be corrected, if the survey is used for acceptance of the identified CC
- The dedicating entity shall establish a survey frequency to ensure that process controls applicable to the CC of the item or service procured continue to be effectively implemented.

Conducting a Commercial Grade Survey (cont.)

- Factors to be considered include:
  - Complexity of the item or service
  - Frequency of procurement, receipt inspection, performance history, and knowledge of changes in the suppliers process and controls.
- The survey frequency may be the same as supplier audits but shall not be used to extend the frequency specified for supplier audits.

Performance-based vs. Compliance-based

Performance-based approach

What equipment is furnished?

What are equipment safety functions?

What are the CC?

-

How are CC controlled?

Are controls adequate and documented?

Are they doing what they committed to do *and* are they doing the right things?

Vendor qualification is "based on performance" and can be graded.

Compliance-based approach

-

-

-

What QA program is the supplier committed to?

How is it implemented?

Do they comply?

Are they doing what they committed to do?

Go or no-go

Preparing for the Commercial Grade Survey

- Determine the scope of the survey based on the commercial grade items to be purchased
- Engineering to provide critical characteristics and/or critical processes (e.g., test control) from the Technical Evaluation for each item within the scope of the survey
- Select the survey team (including an engineer technically competent for subject matter of the survey)
- Coordinate with the supplier and review quality assurance program documents and procedures including supplier controls for preparation, approval and issuance of Certificate of Conformance

Examples of Examining Appropriate Implementation of Quality Controls

Design Control
Do the supplier's controls assure an identical or equivalent item will be provided?

Material Controls
Is the item controlled from receipt through shipment to assure the correct item is being shipped?

Procurement Control
How are items specified to sub-suppliers? How are procured items verified as being conforming to design?

Inspection/Test Control **Are the inspections and tests controlled and conducted by capable people?**

Nonconformance
Are non-conforming materials controlled and properly dispositioned?

Calibration
Is measuring and test equipment controlled in accordance with some program?

Special Processes
How effectively are critical characteristics controlled/imparted during manufacturing?

Certificate of Conformance
Is preparation, approval, and issuance of C of C's properly controlled by procedure?

Addressing Inadequate Supplier Controls

- Determine nature of the inadequacy
  - The supplier does not adequately implement the QA program
  - The supplier is not conforming to current procedures
  - The supplier does not feel the critical characteristic needs to be verified
  - The supplier verifies the critical characteristic, but does not document the verification adequately
- Determine if the supplier is willing/able to enhance the controls to meet customer expectations

Documentation Associated with Survey

- CGI Technical evaluation and dedication plan
  - Identifies the acceptance method
  - Identifies the CCFAs to be verified
- Commercial Grade Survey results/reports
- Standard receipt inspection
  - Supplier Certificates of Conformance

Summary of Acceptance Method 2

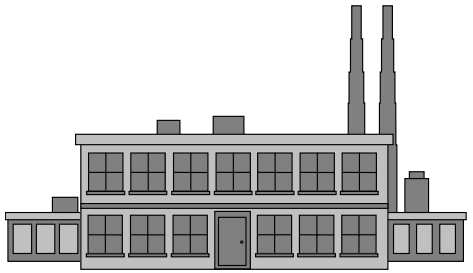
- Reliance is placed on the sub-supplier/manufacturer to verify critical characteristics
- The commercial grade survey validates that the supplier has the appropriate quality controls and they are being implemented satisfactorily
- The commercial grade survey results must be documented for use by engineering

Summary of Acceptance Method 2

- Engineering must specify the appropriate quality controls on each subsequent order
- Evidence that the controls were implemented each time is via supplier documentation (i.e., certificates of conformance)
- Subject to recertification

Acceptance Method 3 – Source Verification

- Purpose
  - To accept a CGI by witnessing at the manufacturer's facility that the supplier controls the critical characteristics. Source verification is applicable only to the actual item(s) or service(s) that are verified at the supplier's facility or other applicable location.
- The purchaser may witness tests or inspections, or may evaluate quality processes as they apply to the critical characteristics of the item being procured



Acceptance Method 3 - Guidance

- When in-process verification of one or more critical characteristics is needed
- When non-conformances have been detected during prior receipt inspections
- When problems/deficiencies exist with the manufacturer's quality assurance program/procedures
- Owner schedule demands
- Single supplier of the item
- Item purchased infrequently

Acceptance Method 3 – Guidance (cont.)

- Used where CC's cannot be easily verified following completion of the design or manufacturing processes
- Used where supplier controls are insufficient for use of Method 2
- Personnel would observe key activities in the design process such as:
  - Verification of design inputs
  - Use of appropriate calculation methods
  - Performance of independent verification and design review activities

Preparing for the Source Verification

- The requirements for CGI are defined in the purchase order which includes supporting technical documents
- Provide CC for each item being procured
- Select the source verifier(s)
- Coordinate with the manufacturer and review quality assurance program documents and procedures, if applicable
- Ensure right(s) of access are specified in the purchase document prior to issue
- Conduct an entrance meeting (If required by verification activities)

Conducting the Source Verification

- Organizations performing source verification shall develop criteria for the personnel qualifications and processes used to perform source verification.
- The source verifier may be an auditor, inspector, engineer, or subject matter expert consultant or combination thereof.
- The purchaser may witness tests or inspections or may evaluate processes as they apply to the critical characteristics of the items being procured
- The items are not released for shipment if the item's critical characteristics are non-conforming.

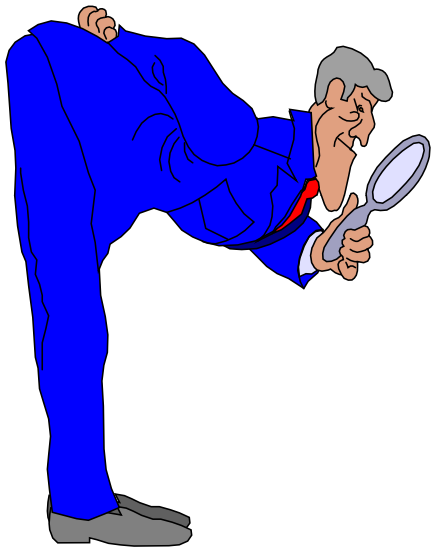
Conducting the Source Verification (cont.)

- Source verification shall be performed in accordance with a checklist or plan with the documented evidence of the source verification furnished to the dedicating entity and shall include or address the following:
  - Identification of item(s) or service(s) included within the scope of the source verification
  - Identification of the CC, including acceptance criteria, being controlled by the supplier
  - Verification that the supplier's processes and controls are effectively implemented for the CCs of that item
  - Identification of the activities witnessed during the source verification and the results obtained
  - Identification of mandatory hold points

Source Verification Activities – Witnessing a Test (Typical)

- Material hardness
- Nondestructive examinations
- Tensile test
- Hydrostatic test
- Leak rate test
- Extent of computer program verification testing
- Extent of challenge testing for programs
- Material type (chemical analysis)
- Calibration
- Operability
- Electrical continuity

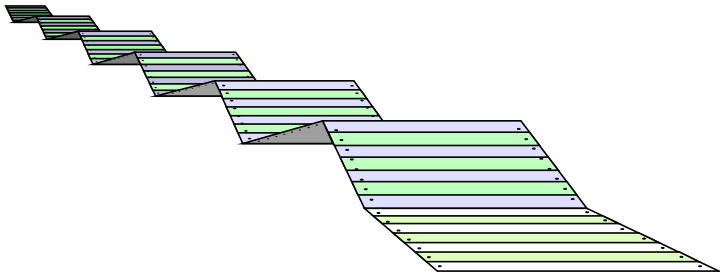
Source Verification Activities – Witnessing an Inspection (Typical)



- Dimensional
- Configuration
- Coating thickness
- Weld

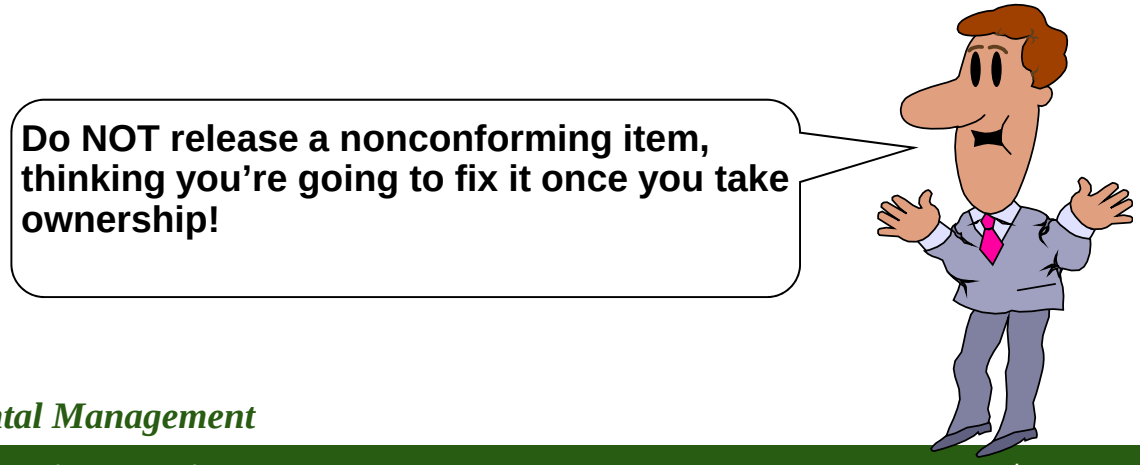
Source Verification Activities – Observing a Process

- Welding
- Assembly
- Insulating
- Coating
- Software design/development
- Heat treatment
- Machining
- Testing



Addressing Inadequate Supplier Controls

- Determine nature of the inadequacy
  - The manufacturer is not conforming to current procedures
  - The manufacturer does not feel the critical characteristic needs to be verified
  - The manufacturer verifies the critical characteristic, but does not document the verification adequately
- Determine means by which the manufacturer can correct the non-conformance



Activities Following the Source Verification

- Conduct an exit meeting (if required by scope of verification activities)
- Prepare and issue the quantified results of the source verification
- Review technical adequacy of the source verification results to ensure all critical characteristics have been properly verified

Documentation Associated with Source Verification

- CGI technical evaluation and dedication plan
  - Identifies the acceptance method
  - Identifies the CC to be verified
- Source verification plan provided to the personnel conducting the source verification
- Source verification plan completed with actual results documented
  - Documentation of the adequacy of the supplier's processes and controls associated with the critical characteristics and acceptance criteria

Summary of Acceptance Method 3

- The purchaser may witness tests or inspections or may evaluate quality processes as they apply to the critical characteristics
- The source verification determines that the manufacturer implements appropriate controls as the items being procured are manufactured
- Source verification alone is applicable only to the actual item witnessed

Acceptance Method 4 - Supplier/Item Performance Record

- Allows the purchaser to accept commercial grade items based upon a confidence in the supplied item achieved through proven performance of the manufacturer.
- Allows purchaser to take credit for item performance based upon historical verification gained from the successful utilization of Methods 1, 2, and 3.
- Based on:
  - User Historical Performance
  - User Historical verification (Methods 1, 2, and 3)
  - Industry Wide Performance – Must be specific and applicable to the item being accepted if it is to be used to establish an acceptable supplier/item performance record.

Implementation of Acceptable Supplier/Item Performance Record

- Product/Performance Test Results
- Institute of Nuclear Power Operations (INPO) Nuclear Parts Reliability Data System
- Seismic Experience/Test Data Bases and Equipment Qualification Data Bank
- Commercial Program Audits/Surveys Conducted by Industry Groups
- Supplier Response(s) to Commercial Grade Program Controls questionnaire
- Utilization of National Codes and Standards
- Should not be a single source of information

Implementation of Acceptable Supplier/Item Performance Record (cont.)

- The purchaser should perform an evaluation of the supplier/item performance record to ensure the performance record or data comes from conditions equivalent to the intended application of the commercial grade item or service including:
  - Environmental condition
  - Failure mode
  - Maintenance program
  - Testing
  - Other conditions

Implementation of Acceptable Supplier/Item Performance Record (cont.)

- Continued application of performance record as a method of acceptance shall include a documented periodic update and review
- An acceptable item or service performance record shall not be employed alone as a method of acceptance unless:
  - Record is based on industry-wide performance data that is directly applicable to the CC and the intended facility application, i.e., single sources of information are not adequate to demonstrate satisfactory performance.
  - The manufacturer's/supplier's measures for the control of applicable design, process, and material change have been accepted by the dedicating entity, as verified by survey.

Implementation of Acceptable Supplier/Item Performance Record (cont.)

- An acceptable supplier item or service performance record shall include the following:
  - Identification of the supplier item or service being evaluated
  - Identification of previously established CC specific to the supplier item or service
  - Identification of data examined to evaluate the supplier item or service
  - Identification of basis for determining that performance data substantiates acceptability of the supplier item or service.
  - Documentation of the adequacy and acceptance of the supplier/item/service performance record

Dedication of Commercial Grade Services

- CGD process can be applied to services such as:
  - Design services
  - Repair and testing services
  - Fabrication/Machining/Cleaning
  - Training
  - Calibration services
- CC for services:
  - Measurable attributes of the impacted item(s) affected by the service and critical for the item to perform its safety function
  - In-process controls of the service critical for the item(s) impacted by the service to perform its safety function

Dedication of Commercial Grade Services (cont.)

- As an alternative to CGD, a service may be performed under the dedicating entity's or other organization's quality program and procedures that meet the requirements of NQA-1
- Physical, mechanical, or other service activities that alter or create new CC of an item that can be used to determine the acceptability of the service that produced the CC shall not be considered a commercial grade service.

Commercial Grade Item/Services Dedication Documentation

- Documentation of the commercial grade item or service dedication process should be traceable to the item, group of items, or services
- Documentation should include the following information depending on the applicable dedication method
  - Dedication plans or procedures including the essential elements of the dedication process
  - Commercial grade item or service procurement documents
  - Technical evaluation of the safety function
  - Critical characteristic identification and acceptance criteria, including or referencing design documents and failure mode analysis

Commercial Grade Item/Services Dedication Documentation (cont.)

- Test reports or results, inspection reports, analysis reports
- Commercial grade survey reports
- Source verification reports
- Historical performance information
- Dedication report containing sufficient data to accept the item or service

DOE TRAINING

Commercial Grade Dedication Training

MODULE 5

Sample Selection Methodology

Applicability of Sampling to CGI Acceptance

- EPRI Report NP-5652 is based on the premise that the combination of the technical evaluation and the acceptance process provides reasonable assurance that the CGI will meet its safety function.
- When sampling is required as a part of the acceptance process, the selection of the appropriate sampling plan complements the critical characteristic selection.
- Because of numerous procurement qualitative factors, it is normally not necessary to perform 100 percent tests or inspections to obtain reasonable assurance.
- Nuclear Facility procurements usually involve quantities that are small relative to large production lots.

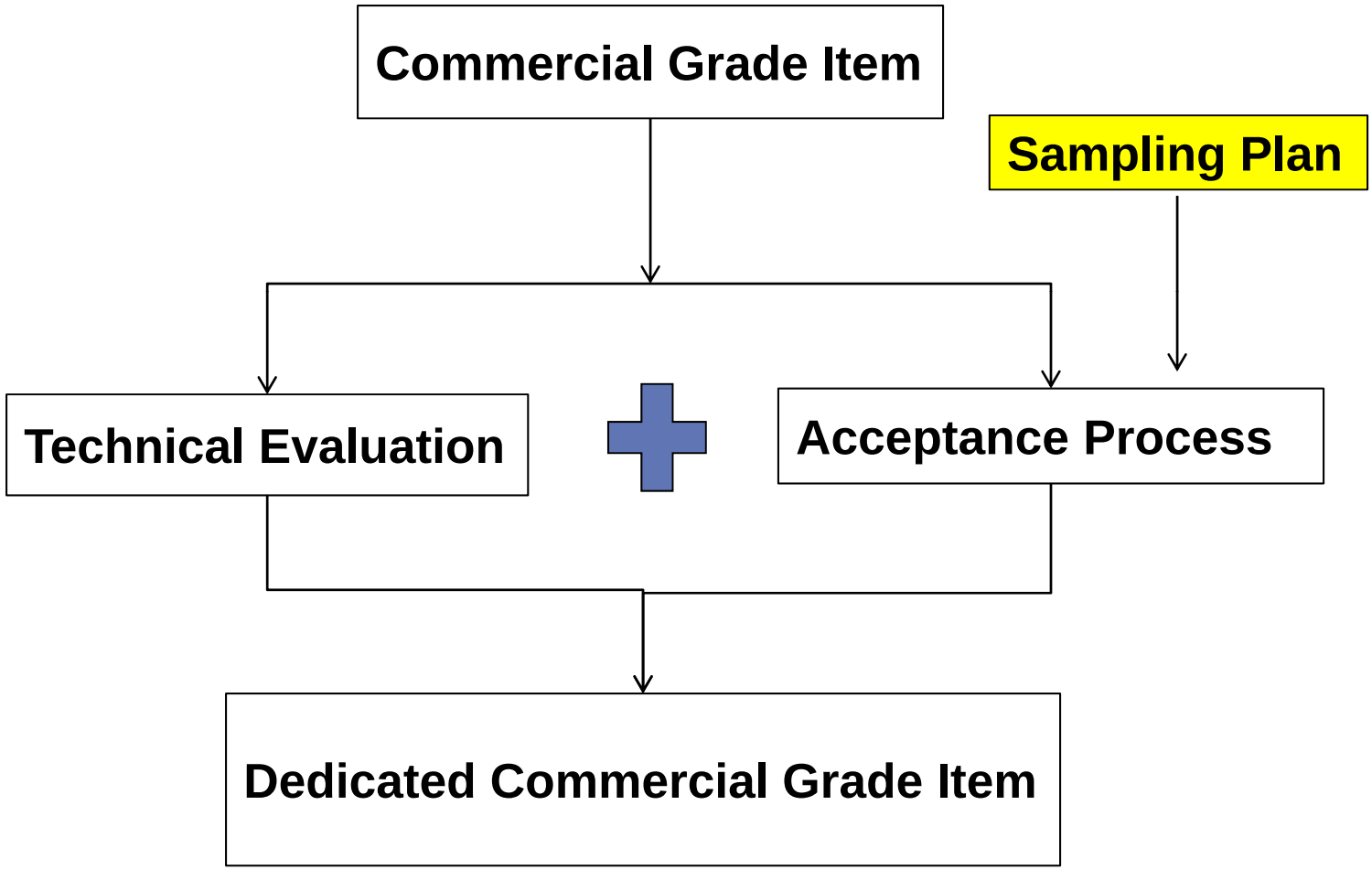
Basic Premises of the Guideline

- Engineering Judgment – Just as in the selection of critical characteristics, sound engineering judgment in the selection of sampling size is a key factor
- Manufacturers' Product Controls – Objective evidence of the supplier's ability to provide acceptable items is a key factor
- Random Sample selection – Each item in the lot has an equal opportunity of being selected as part of the sample

Basic Premises of the Guideline (cont.)

- Acceptance of the Lot – If the sample results are acceptable than there is reasonable assurance that the remainder of the lot is acceptable
- Documentation – The CGI acceptance sampling process and the bases for sampling plan selection and application should be adequately documented

Sampling Methodology



Lot Formation

- Lot homogeneity is typically a matter of degree and not an absolute
- The reason sampling plans can be used when the ideal of production traceability does not exist stem from the statistical structure of sampling plans.
- When a purchase order line item is presented for acceptance, there is reason to assume a certain level of homogeneity.
- The line item is made up of like type items, specified with the same technical and quality requirements, expected to meet the same acceptance criteria

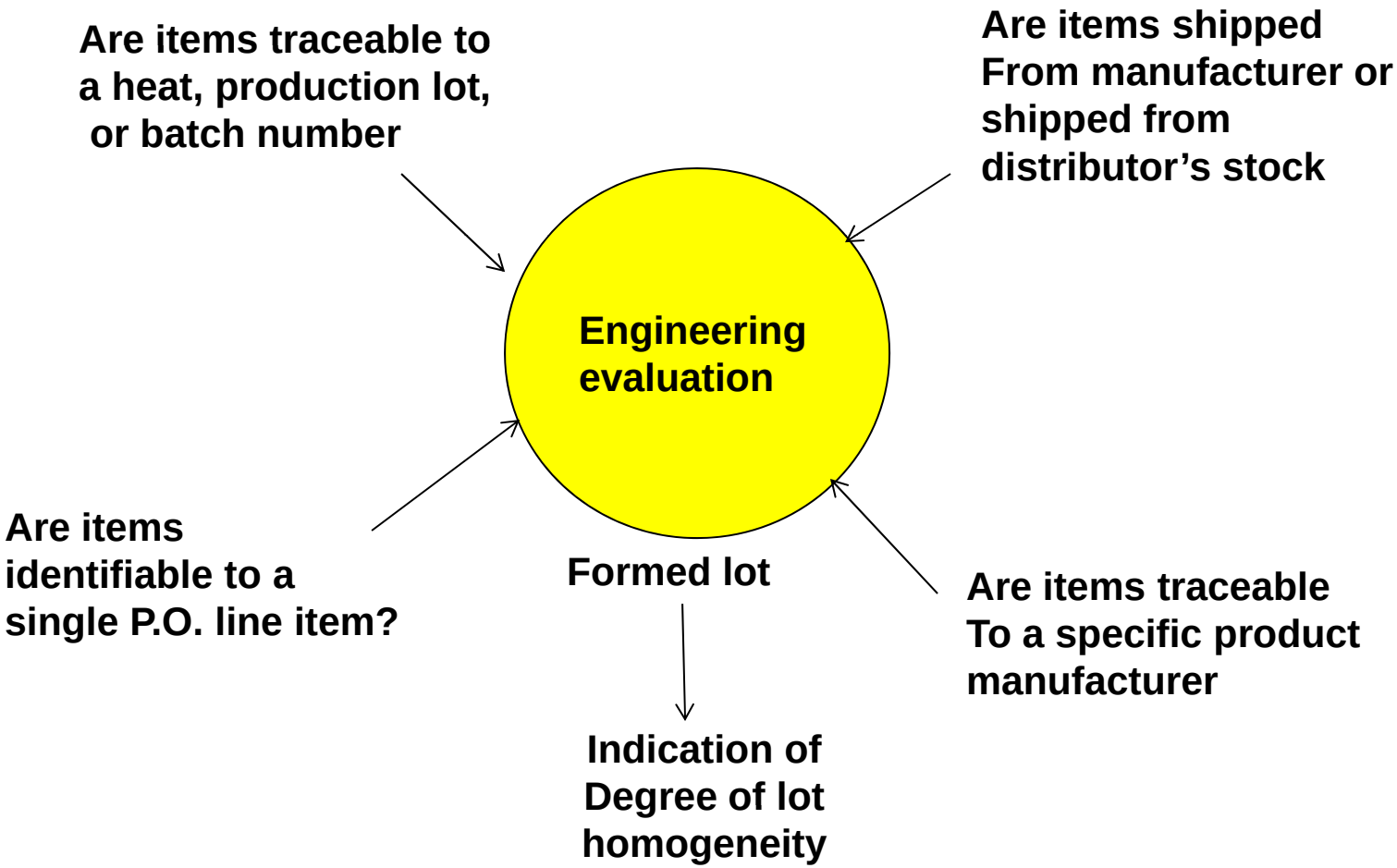
Lot Formation (cont.)

- Additional confidence in lot homogeneity is directly related to how the lot was formed
- Lot formation is typically established in one of the following ways:
  - Production Traceability – heat number, production lot number, or batch number
  - Line Item/Single Manufacture – traceable to a specific purchase order line item and the products are from a single product manufacturer.
  - Line Item/Multiple Product Manufacturers – specific purchase order line item but either different product manufacturers may have produced the item or a product manufacturer does not exist.

Relationship Between Lot Homogeneity and Sample Size

- High confidence the lot is homogeneous, then only a small sample size is needed to provide additional assurance
- Low confidence the lot is homogeneous, then a larger sample size is needed to provide additional assurance

Lot Formation



Sampling Plan Selection Factors

- Product /Supplier Factors
  - Acceptance history of supplier's products
  - Formed lot
  - Item performance history
  - Complexity of the item
  - Applicability of industry standards to the item
  - Supplier controls
  - Safety Significance of the item

Sampling Plan Selection Factors (cont.)

- Testing or Inspection Factors
  - Acceptance method chosen
  - Whether verification technique is nondestructive or destructive
  - Number of other critical characteristics being verified
  - Cost-effectiveness of the test or inspection
  - Correlation between nondestructive and destructive tests

Sampling Plans for Nondestructive Tests and Inspections

- The selection factors listed in the previous slides should be considered when selecting the sampling plan
- Selection of the appropriate sampling plan should be based on the additional level of confidence necessary
- For a given CGI requiring acceptance, different sampling plans can be selected for different critical characteristics
- Sampling plans are:
  - Normal Sampling Plan
  - Reduced Sampling Plan
  - Tightened Sampling Plan

Normal Sampling Plan

- Normal Sampling Plan should be initially considered when selecting a sampling plan for nondestructive tests and inspections
- Factors to consider:
  - The lot will be acceptable based upon available knowledge of the product manufacturer or supplier
  - The lot is expected to have a sufficient homogeneity that a randomly selected sample will represent the whole

Reduced Sampling Plan

- The Reduced Sampling plan should be considered when less discrimination is considered necessary to assure critical characteristic conformance
- Factors to consider include:
  - Acceptance trending provides objective evidence that the product manufacturer or distributor has consistently had a satisfactory product acceptance history
  - The lot formation is based on a product manufacturer's heat number, production lot number, or batch number
  - A satisfactory item performance history exists

Reduced Sampling Plan (cont.)

- Factors to consider include (cont.):
  - Multiple CC are being verified on items in the formed lot from a single product manufacturer (i.e., reasonable to assume that the manufacturer has exercised similar controls over other CC)
  - The item is a standardized product manufactured to a national standard
  - The cost-effectiveness of the test/inspection is low
  - The item is simple
  - The critical characteristic has a low safety significance

Tightened Sampling Plan

- The Tightened Sampling Plan should be considered when more discrimination is considered warranted to assure critical characteristic conformance.
- Factors to consider include:
  - Based upon available information on the manufactured, distributor, or item, there is concern that the lot is nonconforming
  - The lot consists of like-items from multiple or unknown product manufactures

Tightened Sampling Plan (cont.)

- Factors to consider include (cont.):
  - The homogeneity of the lot needs to be assessed to justify small sample sizes for other critical characteristics
  - The item is not produced to a national standard
  - The cost-effectiveness of the inspection/test is high
  - The item is a complex assembly
  - The item has a high safety significance

Sampling Plan Tables for Nondestructive Tests & Inspections

- EPRI TR-017218-R1, Table 2-1 provides the recommended set of nondestructive test and inspections sampling plan tables.
- For all three sampling plans, if a CC of a sampled item does not meet the established acceptance criteria, the sampled item is classified as defective
- The lot acceptance basis is to accept the lot if the sample does not have a defect and reject the lot if the sample has one or more defects

Examples from Table 2-1

	NP	RP	TP
Lot Size	7-11	6-13	12-13
Sample Size	4	2	8

Sample Size Selection for Destructive Tests and Inspections

- When destructive testing or inspection is required to verify a critical characteristic, using the sampling tables 2-1 of EPRI- TR-017218-R1 is not practical.
- The need for smaller sample sizes when destructive testing is involved has been recognized for material testing and equipment qualification testing.
- For CGI, prudent up-front planning to obtain the optimum lot formation available and consideration of the interrelationship between CC can justify smaller sample sizes.

Sample Size Selection for Destructive Tests and Inspections (cont.)

- If the lot to be sampled is all from the same heat number, production lot number, or batch number, then there is a high level of confidence that the items within the lot will have similar properties.

- If you cannot obtain production traceability, then determine if the item can be obtained with a Line Item/Single Product Manufacturer lot formation.

  - If so, then use EPRI- TR-017218-R1, Table 2-2. For example, for lot size 1-10, sample 1. For 71-150, sample 4, for 1271-2550, sample 8 and greater than 2550, sample 9.

Sample Size Selection for Destructive Tests and Inspections (cont.)

- Lot formation with Line Item/Multiple Production Manufacturers should be avoided whenever destructive testing is required.
- If this must be used, then table 2-1 should be used to select sample size.

Sample Plan Implementation

- When destructive testing is required, special consideration should be given to the number and types of test samples needed. May need to adjust order number to accommodate.
- The type of test specimen should be identified prior to issuing the purchase order.
- Once the CC have been selected to be tested and the sample size for each CC has been chosen, there are different approaches for selecting samples.
- Approach A

CC	Sample Size	ID Number
A	8	1, 5, 10, 12, 16, 23, 27, 30
B	8	1, 5, 10, 12, 16, 23, 27, 30
C	8	1, 5, 10, 12, 16, 23, 27, 30

Sample Plan Implementation (cont.)

- Approach B

CC	Sample Size	ID Number
A	8	15, 25, 28, 18, 10, 3, 30, 5
B	8	16, 26, 29, 19, 11, 4, 13, 30
C	8	14, 24, 27, 17, 9, 2, 1, 6

- For Approach A, three critical characteristics would be verified on 27% of the items in the lot. In Approach B, one CC would be verified on 80% of the items in the lot.
- The types of verifications and where they will be accomplished will often dictate whether Approach A, Approach B, or a combination of both approaches is used.

Evaluation of Results

- The lot shall be accepted if the sample has no defects.
- The lot shall be rejected if the sample has 1+ defects.
- Possible actions when one or more defects are found:
  - An additional sample from the remainder of the lot could be selected to determine if the nonconformance is an isolated case or a systemic problem. The additional sample size should be larger than the original sample size.
  - A 100% sorting of the lot could be conducted and would consist of test and inspection of each item in the lot. It could be limited to the nonconforming characteristic or all characteristics. Each item would than be classified as conforming or nonconforming

Evaluation of Results (cont.)

- An engineering evaluation can be performed to disposition the defect(s)
- The lot can be rejected and returned to the supplier in lieu of an engineering evaluation
- If the item is repaired by the supplier or the supplier provides a replacement that is resubmitted for inspection, then an increased or 100% sampling of the previous nonconforming critical characteristic might be prudent.

Documentation

- The CGI acceptance sampling process and the bases for sampling plan selection and application should be adequately documented.
- Documentation should address lot formation, complexity of the item, adequacy of supplier control as appropriate, safety function, test methodology, product performance, acceptance history of a supplier, item performance history, and so on.

Documentation (cont.)

- The following details for CGI acceptance should be considered:
  - Technical basis for sampling
  - Lot size
  - For each CC, that sample size or a reference to the sampling plan
  - Sample results
  - Lot disposition

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MODULE 6

Supplier Dedication Oversight

Enabling Objectives

- Describe basic elements under which an NQA-1 supplier performs CGD for a Commercial Sub-Supplier
- Describe how an NQA-1 supplier should implement a CGI/CGS dedication program
- Describe appropriate activities to perform to review suppliers' dedication activities

Commercial Grade Dedication – Supplier Submittals

- Suppliers may be requested to submit procedures or dedication plans when
  - the dedication program requires supplemental assistance
  - when the significance or complexity of the item warrants oversight
- Supplier submittals related to CGD to consider:
  - CGD procedure
  - CGD test/inspection plan for items requiring dedication
  - Supplier's dedication procedure (Does it address the technical evaluation and acceptance planning processes effectively?)
  - Verify that technical evaluation process determines safety function or includes the information from the purchase order

Commercial Grade Dedication – Supplier Submittals (cont.)

- Verify that the technical evaluation associated with the safety function results in a logical selection of critical characteristics and acceptance activities commensurate with the significance of the item
- Verify that the supplier inspection, test, sub-supplier audit and source verification activities are prescribed in a concise manner and conducted and documented in a manner that captures the intended results
- Tests results for CGD related tests and inspections as identified by the CGD plan

Review and Acceptance of Supplier Submitted CGD Procedures

- Submittal review must include an understanding of the scope of the CGD activity
- Scope of Supply Cases:
  - Case 1. Supplier performing CGD as Fabricator
  - Case 2. Supplier performing CGD as both Design and Fabrication and procuring and dedicating items from commercial suppliers

Case 1. NQA-1 Supplier Performing CGD as Fabricator – Scope & Submittals

- Responsible for fabrication and delivery of an item designed by a higher tier supplier
- Responsible for ensuring design requirements are met by the delivered item
- CC defined in drawings, specifications, and other design documents provided by designer
- The Fabricator should be provided with the CCFA or provided with sufficient safety function, design characteristics, and mode failure analysis information to develop the CGD package

Case 1. NQA-1 Supplier Performing CGD as Fabricator – Scope & Submittals (cont.)

- The Fabricator's CGD program needs to be evaluated as part of the Fabricator's NQA-1 program acceptance and placement on the evaluated supplier's list
- The CGD package needs to be approved by the buyer through the procurement submittal process
- Scope items: obtaining base metals, simple items (flanges, fittings, piping, weld materials, gaskets, seals)
- Focus on material properties, dimensions

Case 2. NQA-1 Supplier Performing CGD as Both Design & Fabrication Scope

- Procuring and dedicating items of greater complexity from commercial suppliers such as pumps, valves, or electrical and instrumentation equipment
- CGD process must include the development and documentation of design documents from the analysis of safety functions; and then selection of appropriate CC as the basis for item acceptance

Case 2. NQA-1 Supplier Performing CGD as Both Design & Fabrication Scope (cont.)

- Purchaser reviews scope of supplier dedication activities required to be met and evaluates supplier CGD procedures, work instructions, and forms considering the following:
  - Has supplier been approved to perform CGD Technical Evaluations by Supplier Quality through supplier survey activities?
  - Does the supplier's CGD process contain the correct level of detail for their sub-supplier's scope of supply?
  - The CGD package needs to be approved by the Buyer through the procurement submittal process

Supplier CGD Plans and Test Results – Review Considerations

- Supplier CGD Plans
  - Basis for selection of CC, acceptance methods, acceptance criteria
  - Reasonable assurance that plan implementation will result in items ordered are received and they perform required functions
- Supplier Test Results
  - Tests properly document completion of acceptance activities and dedicated items meet acceptance criteria
  - Do tests results include post-receipt or post-installation test, inspection or analysis requirements that must be tracked to completion?

Expectations Regarding CGI Dedications by NQA-1 Suppliers

- Supplier must have an appreciation for:
  - The most severe end use application
  - Accident conditions under which the item must function
  - The safety functions of the host equipment and the item
- Supplier must select and verify a set of critical characteristics that provides reasonable assurance that the item will perform its intended safety function

Expectations Regarding CGI Dedications by NQA-1 Suppliers

- Supplier has the same flexibility as the purchaser in selecting optimum means of CC verification
  - Source inspections of sub-suppliers/manufacturers
  - Audits/surveys of sub-suppliers/manufacturers
  - Tests/inspections of the CGI
  - History of Performance
  - “Trust But Verify”

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MODULE 7

Overview of CGD Process of Computer Program and Digital Equipment

Course Objectives

- Define the terms for computer program, firmware, and digital equipment
- Understand the process for CGD of digital equipment with embedded computer program and stand-alone computer program
- Describe the bases for implementing each element of the generic process for CGD of computer program and how they relate to NQA-1 requirements and EPRI Guidelines
- Understand the acceptance process for computer program and how it might differ from CGD of hardware type items and services

Overview

- CGD of software (computer programs) and digital equipment is performed in accordance with ASME-NQA-1a-2009 with additional guidance from EPRI TR-106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications
- Based on ASME NQA-1, CGD of computer program, whether embedded or non-plant equipment computer programs (stand-alone), still must be performed using the same two fundamental processes as standard CGD previously discussed
  - Technical Evaluation
  - Acceptance Process

Definitions

- Computer Program – A combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions. [ASME NQA-1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications," who used definition from ANSI/IEEE 610.12-1990, "Glossary of Software Engineering Terminology", with permission of IEEE]
- Firmware – Software that resides in read-only memory. [Adapted from IEEE 7-4.3.2-1993]
- Hardware – With respect to a digital computer, the physical equipment used to process, store, or transmit computer programs or data. [ANSI/IEEE 610.12-1990]

Definitions (cont.)

- Human-machine interface (HMI) – Any interface between the instrumentation and control system or equipment and the plant personnel including operators, maintenance technicians, and engineering personnel
- Safety Software – Includes; Safety system software, safety and hazard analysis software and design software, and safety management and administrative controls software. [DOE O 414.1C, Quality Assurance]
- Software – computer programs, associated documentation, and data pertaining to the operation of a computer system. [ASME NQA-1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications," who use from ANSI/IEEE 610.12-1990, "Glossary of Software Engineering Terminology", with permission of IEEE]

Computer Program Technical Evaluation

- Complete translation of design requirements into critical characteristics for CGD of computer program is key to successful dedication. Should include:
  - Hardware
  - Computer program
  - HMI
  - Quality
  - Reliability

Computer Program Technical Evaluation (cont.)

- When performing CGD of computer programs, in addition to design requirements for the intended functions and anticipated failure modes, it is important to identify requirements related to unused, and unintended or prohibited functions.
- Critical characteristics fall under four general types:
  - Identification, Physical, Performance, and Reliability

Identification Characteristics

- Identification Characteristics of the hardware and computer programs are similar to mechanical, electrical, and analog electronic equipment.
- Would include characteristics such as;
  - Host computer operating environment
  - Host computer operating system identifier
  - Computer software Name
  - Computer software Version Identifier

Physical Characteristics

- Physical characteristics of the hardware such as size, mounting, and other characteristics are similar to mechanical, electrical, and analog electronic equipment
- There are some differences due to the need to verify computer program or firmware revision.
- Most of these characteristics are verified using inspection and measurement, which falls under Method 1

Performance Characteristics

- Performance characteristics include functionality required of the device (the “must-do” functions) and performance related to the functionality (e.g., response time)
- Also include environmental requirements related to the needed performance
  - Meeting accuracy requirements over a specified range of ambient temperatures

Performance Characteristics (cont.)

- The acceptance criteria and verification methods for performance characteristics are similar to those for hardware, electrical, and analog equipment
- This category also includes characteristics related to failure management and “must-not-do” functions.
- Verification methods include testing and design reviews, supported by failure analysis and reviews of operating history.
  - Involve Method 1, Method 2, Method 3, and Method 4.

Reliability Characteristics

- Reliability category is the category in which dedication of digital equipment and/or computer programs differs the most from that of other types of items and services
- Addresses attributes that typically cannot be verified through inspection and testing alone and are generally affected by the process used to produce the device or computer program.
  - Hardware failures are usually associated with fabrication defects, aging, and wear-out. Computer programs do not physically wear-out but they do wear out with respect to becoming obsolete or no longer supported by the manufacturer.
  - Computer program failure is usually a design error that was built into the device, or a mismatch between the application requirements and the device design.

Reliability Characteristics (cont.)

- In traditional dedications of mechanical and electrical equipment, dependability issues have been treated within the supplier's QA program and have been delineated in the commercial grade survey or source inspection plan.
- Due to the increased importance of these built-in attributes to a digital device or computer program, dependability attributes are defined as critical characteristics to ensure that they are adequately addressed and documented during CGD.

Reliability Characteristics (cont.)

- Reliability and built-in quality are strongly influenced by the process and personnel used by the supplier/developer in the design, development, verification, and validation of the computer program-based equipment.
- For computer program based systems, high quality is best achieved by building it in, following a systematic life cycle approach from requirements through implementation, with verification and validation steps and appropriate documentation for each phase of the life cycle.
- Understanding the developer's development process can be very useful in developing the confidence in the dependability of a product.

Reliability Characteristics (cont.)

- The reliability of a digital device also can be heavily influence by designed-in elements such as;
  - Robustness of the hardware and computer program architectures
  - Self-checking features such as watch dog timers
  - Failure management schemes such as use of redundant processors with automatic fail-over capabilities.
- May require gaining an understanding of the specific computer program and hardware features embodied in the design, and ensuring that they are correct and appropriate in light of the requirements of the given application.
  - Survey team should include specialists who understand device design, computer program(s), the system, in addition to QA and program issues

Reliability Characteristics (cont.)

- In addition to built-in quality, dependability also includes characteristics related to problem reporting and configuration control.
- Verification of these characteristics typically involves a survey of the supplier/developer's processes (Method 2), and review of the supplier/developer's performance record and product operating history (Method 4).
- Source inspections (Method 3) may be used to verify certain hardware quality characteristics during manufacture, or to ensure quality of changes made to computer program as part of a particular procurement.

Reliability Characteristics (cont.)

- Reliability CCs are somewhat different from those in the other categories because they are less tangible and quantifiable than a part number or a physical dimension.
- Commercial products may be judged to have sufficient quality, even if the development process lacks some of the rigorous steps of modern computer program engineering and/or some formal documentation.
- Reaching a “reasonable” level of assurance for computer programs/digital equipment typically involves making a judgment based on a combination of;
  - product development, operating history, testing, review of design features such as failure management, and documentation.

Built in Quality

- Review of the design, its documentation, and hardware and computer programs implementations
  - Design and documentation:
    - Completeness
    - Accuracy and consistency with actual design
    - Overall system design and computer program architecture:
    - Simplicity
    - Determinism of program execution, control flow and data flow
    - Internal consistency
    - Adequacy to support needed functionality
    - Unneeded features and their impact on the required functionality
    - Error handling capabilities, built-in protective features, ability to handle expected and unforeseen errors and abnormal conditions & events (ACEs)
    - Human factors and the HMI
    - Protection against EMI-induced and other errors

Built in Quality (cont.)

- Review of the design, its documentation, and hardware and computer program implementations, cont.
  - Computer program implementation:
    - Structure of code
    - Adherence to accepted coding practices
  - Hardware implementation:
    - Use of good manufacturing practices
    - Quality of components used

Built in Quality (cont.)

- Review of the design/development process and its documentation, as it was applied for the item being evaluated.
  - Life cycle used for product development, verification and validation
    - Consistency with accepted standards and guidelines (e.g., IEEE standards, EPRI TR-103291)
  - Adequacy of computer program/hardware requirements:
    - Completeness
    - Correctness
    - Clarity
  - Traceability from system requirements and design through computer program requirements, computer program design, code, and validation testing

Built in Quality (cont.)

- Review of vendor QA program and practices, including software QA (SQA)
  - Documented QA program:
    - Consistency with NQA-1a-2009 and relevant standards (e.g., IEEE)
  - Vendor program certifications (e.g., ISO 9000, European certifications)
- Application of QA program to item being procured:
  - How strictly the program was adhered to for this product, degree of buy-in by personnel involved
  - How well documented, how formal, approvals required

Built in Quality (cont.)

- Design reviews and verifications:
  - Extent and coverage of reviews and analyses (design reviews, code walkthroughs and inspections, use of analytical tools)
  - Independence of reviewers and verifiers
- Systematic application of lessons learned from problems experienced with earlier versions of the product

Built in Quality (cont.)

- Review of qualifications and experience of personnel involved in design and verification
  - Individuals:
    - Training in areas related to design or verification responsibilities
    - Experience in similar projects
    - Familiarity with specific tools, languages, etc., used in design
  - Organization:
    - Experience in developing similar products
    - Third-party certifications as they relate to organizational capabilities

Built in Quality (cont.)

- Review of vendor configuration control program and practices
  - Documented configuration management program:
    - Consistency with relevant standards and accepted practices (e.g., IEEE)
  - Vendor program certifications (e.g., ISO 9000, European certifications)
  - Application of configuration management program to item being procured:
    - How strictly the program was adhered to for this product
    - How well documented, from initial development through changes and releases

Built in Quality (cont.)

- Application of configuration management program to item being procured, cont.:
  - Control over sub-vendors
  - Control over distributors or suppliers through which the procured items pass
- Vendor and product track record for control of changes and versions, and notification of changes, especially in repair.

❑ Failure analysis

- Consideration of ACEs in system design and verification:
  - Potential failure modes of hardware and computer program specifically identified
  - Formal or informal hazard or ACEs analyses
  - How early in the process, and degree to which these guided design and verification
- Predictability of failure modes of the device

Built in Quality (cont.)

- Review of vendor testing
  - Functional and performance testing
  - Environmental testing including electromagnetic interference (EMI) and radio frequency interference (RFI)
  - Extent of computer program verification testing (e.g., module, line, or branch coverage)
  - Extent of validation testing (e.g., static dynamic, random)
  - Extent of challenge testing (e.g., tests specifically designed to uncover failure modes)
  - Documentation of testing

Built in Quality (cont.)

- Review of product operating history
  - Documented:
    - Records indicating specific models and computer program/firmware versions installed, when, and where
    - Formal or informal problem reports, description of problem and follow-up action
  - Sufficient:
    - Number of units in service
    - Number of years of service

Built in Quality (cont.)

- Successful:
  - Error tracking shows good performance
  - Error rate has stabilized, no critical errors, computer program stable other than feature changes
- Relevant:
  - Same or similar computer program/hardware configuration, and functions or options used
  - Device installed and operated in a manner similar to the planned application
  - Similar environmental conditions
  - Similar run times

Critical Characteristics Development

- The DOE Guide for Commercial Graded Dedication, Appendix D, Table D-1, provides a discussion of Critical Characteristics for Digital Equipment, Imbedded Computer program(s), and non-plant equipment computer programs (stand-alone)
- The Table provides information to cover all four major areas of critical characteristics,
  - Identification, Physical, Performance and Reliability
- The Table presents the information in four topics
  - CC, general description, acceptance criteria, and method of acceptance

Critical Characteristics Development (cont.)

- General information, of most possible characteristics
- Example Information:
  - Under Physical Characteristics
    - Interfaces: Critical input parameters and valid ranges
  - Description
    - The set of input parameters that are used in the critical functions of the computer program and the range of their valid values. This critical characteristic is important to all computer program types to ensure that the computer program will function properly for all possible operational inputs.

Critical Characteristics Development (cont.)

- Acceptance Criteria
  - As described in computer program requirements or procurement specification documentation. This criteria may be;
    - input voltage (e.g., 1.5 to 2.8 volts),
    - deposition receptor height (e.g. 0 to 1 ft),
    - time: (dd/mm/yyyy hh:mm:ss); and/or
    - length (1.00 to 5.00 meters).

Critical Characteristics Development (cont.)

- Method of Verification
  - Verified through a combination of one or more:
    - Inspection and Testing (Method 1)
    - Review the implementing process and controls (Method 2)
    - Observation and review of design and or implementation (Method 3)
    - Review the installed base to determine performance history (Method 4)

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MODULE 8

Implementation and Lessons Learned

Enabling Objectives

- Provide basic general examples of types of CGD activities and how dedication could be approached
- Provide lessons learned from DOE and Prime Contractor oversight of CGD

CGD Example #1: FASTENERS

- Item
  - .5” X 1.0” UNC-2A heavy hex screw per ASTM A193 Grade B8M, Class 1
- Application
  - Items are stocked for use in plant wide applications
- Safety function, service conditions and design margin
  - Service loading that would rely upon the screw having the full mechanical properties for high temperature or high pressure service or other special purpose applications with corrosion resistance as stated in ASTM A193.

CGD Example #1: FASTENERS (cont.)

- Safety significance
  - The bounding condition for the screw is being relied upon for severe service conditions including maintenance of pressure boundary and seismic qualification, therefore a high level of confidence in the item's quality is necessary
- Critical characteristics
  - Dimensions:
    - Diameter, length, threads
  - Chemical content:
    - Carbon, Manganese, Phosphorus, Sulfur, Silicon, Chromium, Nickel, Molybdenum
  - Mechanical Properties:
    - Tensile strength, Yield strength, Elongation, Reduction of Area, Hardness

CGD Example #1: FASTENERS (cont.)

- Acceptance Methods:
  - Dimensional testing in accordance with ASME B18.18.2M is performed
  - Chemical analysis and mechanical properties are verified per ASTM F593.
- Basis:
  - This material is manufactured to ASTM A193.
  - This standard has acceptance criteria established for the physical, chemical, configuration and dimensional characteristics required for the fasteners.
  - The application of the standard such that confidence is established that the acceptance criteria in the standards are met.

CGD Example #1: FASTENERS (cont.)

- The supplier program will maintain material heat traceability and manufacturing lot traceability.
  - Every lot of material will be independently tested using approved sample size, giving a high level of confidence in the material properties.
  - A commercial grade survey will be performed on the fastener manufacturer to evaluate the quality program for controlling forming and machining activities.
  - An inspection will be performed at the supplier's facility on the first lot of items ready for shipment.
- Taken together, these activities provide a high level of confidence in the items supplied.

CGD Example #2: MANUAL GATE VALVE

- Item
  - 1” gate valve per ASME B16.34, hand wheel, Class 600, socket weld ends, ASTM A105 material, Valvco model 0829.
- Application
  - Service water system intertie line drain valve
- Safety function, service conditions and design margin
  - The valve serves as service water system pressure boundary with disc closed during operation. The service water system provides cooling for plant safety components that perform critical functions. The service water system has 150% capacity with one of six pumps in reserve.

CGD Example #2: MANUAL GATE VALVE (cont.)

- The valve will be closed when the system is in service and only opened during maintenance.
- Service conditions are 85 psi at 88F for fresh lake water. The valve is rated at 1350 psi at 100F.

❑ Safety significance

- Maintenance of service water system boundary is important to plant equipment function. The safety significance of this valve is low considering:
  - o available design margin of over 1000 psi
  - o large system flow capacity margin
  - o a failure mechanism considering the design margin of seat or stem leakage that would result in a small amount of service water loss

CGD Example #2: MANUAL GATE VALVE (cont.)

- Critical characteristics:
  - Dimensions:
    - socket weld end diameter and depth
    - body and bonnet wall thickness
    - body - bonnet fastener diameter, threads, length
    - disc thickness, diameter
    - seat diameter, width
  - Material:
    - Body, disc and bonnet compliance with SA105
    - Fastener compliance with SA193/SA194
  - Assembly and Test Related Process Controls
    - Work control
    - Nondestructive examination control
    - Test control
    - Document Control

CGD Example #2: MANUAL GATE VALVE (cont.)

- Acceptance Methods:
  - A survey was performed to evaluate the suppliers quality program for the following:
    - Procurement control for acceptance of purchased forgings and fasteners
    - Work control for fabrication of valve parts from purchased material and assembly
    - Inspection and test control for dimensional verification activities and hydrostatic and seat leakage tests per ASTM B16.34
    - Nondestructive examination control for qualification of personnel and compliance with ASTM standards for performance
    - Nonconformance control for segregation of defective items
    - Document control to assure use of the appropriate drawings and procedures
    - The supplier is required to provide certification with shipment of the valve that the valve was processed under their approved QA program.

CGD Example #2: MANUAL GATE VALVE (cont.)

- Basis:
  - This is a standard commodity valve manufactured to meet ASME B16.34.
  - It was selected by the system design engineer for this application considering the ratings in ASTM B16.34 in relation to the service conditions
  - The commercial grade survey determined that the valve manufacturer placed appropriate controls on their supplier to assure that appropriate assurance of material quality was achieved for the pressure retaining items.
  - ASTM B16.34 requires hydrostatic testing and seat leakage that are incorporated in the supplier's procedures that were evaluated during the program survey.

CGD Example #3: SERVICE

- Service:
  - Qualification testing for building exterior wall siding system
- Application:
  - Emergency diesel generator building
- Safety function, service conditions and design margin
  - The safety function of the wall is to protect the diesel generator from the effects of wind and associated high speed debris impingement. The building must remain intact and protect the diesel generator from an 111 mph wind and a 15 pound piece of 2 x 4 lumber traveling at 50 MPH.

CGD Example #3: SERVICE (cont.)

- Safety significance
  - The building function is to protect the integrity of the diesel generator who's function is to provide backup power to plant cooling and off gas filtration systems, thus the building wall importance is high. The qualification test is critical to establishing the suitability of the design and will serve the basis upon which the following material and installation acceptance activities will be performed.
- Critical characteristics
  - The supplier will be required to perform the qualification test in accordance with the methodology stated in industry standard FM 7882 in line with the application.

CGD Example #3: SERVICE (cont.)

- Acceptance Methods
  - A source surveillance will be performed by the Design Engineer at the supplier's facility to:
    - Review the supplier's test procedure for compliance with FM 7882
    - Witness each step of the test to verify performance in accordance with the approved procedure
    - Verify that the equipment used for the test is calibrated
    - Verify that results are accurately captured
- Basis
  - Considering the criticality of the test, a high level of oversight of the supplier's activities was warranted. Each step was observed by the Design Engineer for compliance with his expectations in the contract.

Lessons Learned

- "Safety" classification MUST precede the determination of procurement category
- "Safety" classification is NOT determined by the supplier
- "Safety" classification is NOT based on whether the item is supplied as ASME NQA-1 or CGI
- Even though original component specifications did not identify a particular sub-item or its critical design characteristics, it doesn't mean there are no CC's of the item that are important requiring verification.

Lessons Learned (cont.)

- Once selected, each CC must be adequately verified
- Not every technical requirement specified in a procurement document may need to be verified as a CC
- Failures of commercial grade items shall be documented and trended
- Methods for controlling, tracking and evaluating failed items shall be procedurally defined and controlled
- Information can be used to adjust the sample size (from one item up to 100%)

Lessons Learned (cont.)

- Dedication Planning Includes Specific Inspection/Test/ Survey Criteria.

  The output of the dedication planning should include specific information that is directly useable by the organization performing the acceptance activity.

  DON'T – State "Test valve to ASME B16.34"

  DO – State "Perform a hydrostatic test of the valve body at 300 psi. Hold the pressure for 10 minutes then inspect for leakage. No leakage is allowed."

Lessons Learned (cont.)

- Understand Suitability versus Dedication
  - Suitability is part of the design process and evaluates an item for it's intended service
  - Suitability establishes the technical basis for the item being able to perform it's functions in the system
  - Dedication includes the technical evaluation for dedication
  - Dedication acceptance planning can be performed based on the approved design documents

Lesson learned – Do not incorporate suitability/qualification testing in dedication activities. For example, the dedication activities should not include "Perform environmental qualification to IEEE - 323-1974."

Lessons Learned (cont.)

- Dedication Planning Packages Do Not Need to Include a Compilation of All The Prescribed Inspection and Test Activity Results

  - The activities prescribed in the dedication planning package are performed by the groups stated in accordance with their normal work performance procedures and the associated records are captured as specified by those procedures. It is not necessary to also have those records included with the dedication planning package for the items.

  - NQA-1a-2009, Subpart 2.14, Section 800 states that test reports or results, inspection reports, and analysis reports are part of the CGD documentation.

Lessons Learned (cont.)

- Dedication Planning Packages Do Not Need to Include a Compilation of All The Prescribed Inspection and Test Activity Results (cont.)

  Lesson learned - An effective dedication process integrates planning activities into existing procedures without causing unnecessary duplication.

  DON'T – Have additional copies of inspection test reports also sent to Procurement Engineering to be placed in the dedication planning package.

  DO – Have inspection test reports documented as directed by the governing procedure and referenced in the CGD package.

Lessons Learned (cont.)

- Industry Guidance Documents are Just that – Guidance
  - Guides are tools to be used to develop a program and to be used by a Procurement Engineer to do individual evaluations.
  - Each dedication activity is based on plant application and the technical evaluation of the critical characteristics.
  - The rigor of the acceptance activities are commensurate with the safety significance.

Lessons Learned (cont.)

- Industry Guidance Documents are Just that – Guidance (cont.)

  DON'T – Adapt EPRI Joint Utility Task Group (JUTG) Commercial Grade Item Evaluations as prescriptive consensus methods for dedicating the items addressed.

  DO – Use the evaluations as a compilation of information related to an item to assist in the performance of the technical evaluation, and therefore select characteristics relevant to the plant application.

Examples of CGD Issues

- Failure to recognize the need for a CGD activity to support the procurement process
- Implementing procedures were expert based instead of being developed at the level of detail to support the knowledge and experience level of the organization performing the activity.
- Lack of understanding of the relationship between the safety function, design criteria, critical characteristics, acceptance criteria, and methods for acceptance.

CGD Benchmarking Lessons Learned

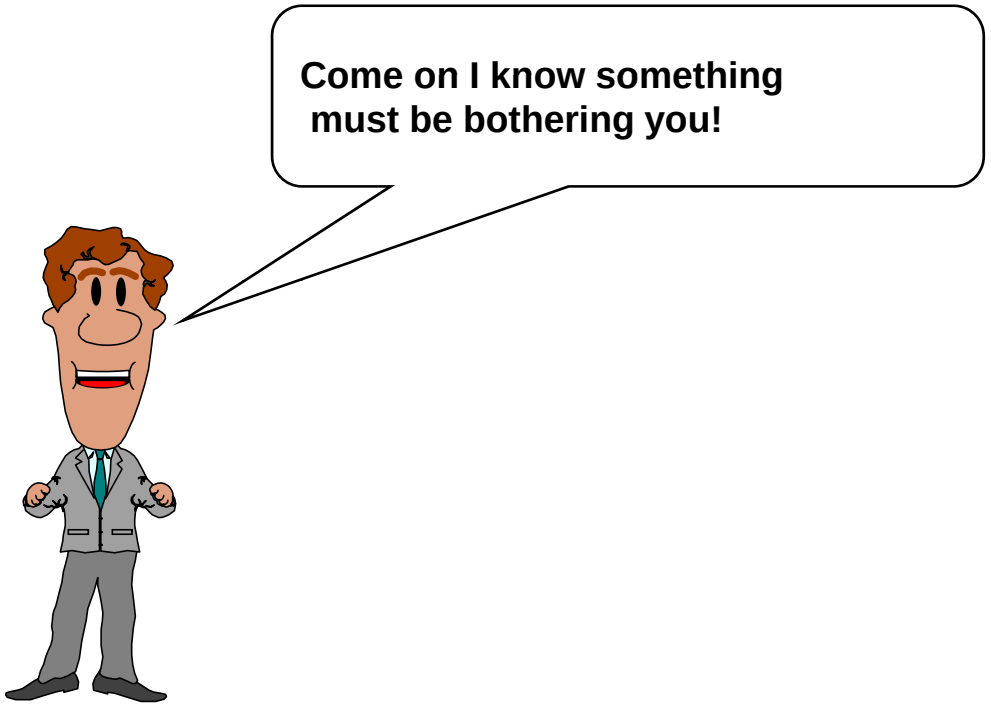
- Several positive lessons learned were identified during the review of three commercial power organizations.
  - Utilities have adopted the Electric Power Research Institute (EPRI) NP-5652, Guideline for Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07), as the basis for conducting CGD activities.
  - Utility engineering organizations develop the CGD critical characteristics and acceptance requirements based on a detailed technical evaluation.
  - Utility quality organizations are responsible for assuring implementation of the CGD requirements.

CGD Benchmarking Lessons Learned (cont.)

- Utilities stressed early communication and integration of CGD team (Engineering and QA).
- Utilities have implemented Engineering Organization CGD training programs
- Utility QA organizations rely on nuclear power industry QA/quality control training programs
- Utility use of CGD surveys to identify/correct supplier commercial quality program concerns prior to procurement

Questions & Answers

Questions or Comments



References:

- DOE Order 414.1C, Quality Assurance
- DOE Guide 414.1-2A, Quality Assurance Management System Guide.
  - Discusses using a recognized international consensus standard for conducting Commercial Grade Dedication
- ASME NQA-1-2004 with addenda through 2007
- ASME NQA-1-2008 with addenda through 2009
- EM Corporate QA Program EM-QA-001 Revs. 0 and 1
- EM Guidance for Commercial Grade Dedication, September 2011

References (cont.)

- EPRI Documents requiring purchase:
  - JUTG Commercial Grade Item Technical Evaluations
  - Information for Use in Conducting Audits of Supplier Commercial Grade Item Dedication Programs
  - Generic Qualification and Dedication of Digital Components: Project Status and Lessons Learned
  - Generic Qualification/Dedication of Digital Components: Summary of 2004 Generic Qualification Activities
- Documents free of charge:
  - Generic Topic of Commercial Grade Dedication:
    - Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)
    - Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items

References (cont.)

- Critical Characteristics
  - Guideline for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11), NP-6404
  - Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)
- Digital Equipment
  - EPRI TR-106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications.
- Sampling Plan Development
  - EPRI TR-017218-R1, Guideline for Sampling in the Commercial-Grade Item Acceptance Process

References (cont.)

- NRC Generic Letter 89-02: Conditionally endorses EPRI NP-5652, Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07). Promotes the use of method one, test and inspection, and if method two or four are used they must be used in conjunction with additional methods.
- NRC Generic Letter 91-05: Defined critical characteristics. The Enclosure provided characteristics of effective commercial-grade procurement and dedication programs.

References (cont.)

- NRC Inspection procedure 38703, Commercial Grade Dedication
- NRC Inspection Procedure 43004, Inspection of Commercial-Grade Dedication Programs
- NRC Inspection Procedure 38703 and 43004, Assessing Sampling Techniques
- www.em.doe.gov/Pages/qualityassurance.aspx